Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

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Abstracts

Critical Review of the Literature

Objectives: Non-suicidal self-injury (NSSI) is associated with several physical and social harmful consequences and has been found to be comorbid with other clinical presentations, including eating disorders. Models have been developed to understand the functions and risk factors of NSSI only, but it is unknown whether they apply to NSSI in the context of people with eating disorders.

Methods: To investigate the risk factors and functions of NSSI in eating disorders, a systematic search was conducted leading to the identification of two longitudinal papers related to risk and six papers related to function, across 666 unique participants.

Results: Affective lability and variation in affective activation were identified as risk factors. NSSI primarily served the functions of emotion regulation, self-punishment, identity formation and self-criticism arising from perceived parental criticism and the failure to meet high standards based on perfectionist traits.

Conclusions: These risk factors and functions fit well with the intrapersonal and interpersonal vulnerability factors identified for NSSI and highlighted other factors, including perfectionism and identity confusion. These may interact with the reinforcing functions of NSSI and lead to the engagement of NSSI alongside ED behaviours.

Service Improvement Project

Objectives: Dialectical behavioural therapy (DBT) is an effective treatment for people with borderline personality disorder (BPD) to help with difficulties they may experience in affect, behaviour and interpersonal relationships. This study aimed to expand upon previous literature by exploring both client and staff perspectives of DBT, of a dual diagnosis DBT service that takes an integrated approach to concurrently treat both the symptoms of BPD and comorbid substance misuse.

Methods: Questionnaires and individual interviews were completed by four clients. Questionnaires were completed by six team members and five of those also completed individual interviews.

Results: For clients, results showed that they rated having a high level of satisfaction with the service and thematic analysis identified three main themes: 'Building a life worth living', 'Challenging aspects of DBT' and 'The therapeutic environment'. Team members rated their delivery of DBT to be of good quality and felt that clients appeared to be satisfied. Thematic analysis identified two superordinate themes: 'Not a dedicated DBT service' and 'Provision of DBT'.

Conclusions: Recommendations made to the service included improving phone support and the presentation of skills to clients. Additional recommendations made included improving the measurement of outcomes and bringing structure to consultation meetings.

Main Research Project

Objective: Negative subjective interpretations about the cause and consequences of physical symptoms is linked to psychological distress amongst cancer survivors. The present study aimed to extend upon previous literature by examining the role of mental defeat, fear of cancer recurrence (FCR) and health-related beliefs on psychological distress and quality of life, in cancer survivors who experience cancer pain and/or cancer-related fatigue (CRF).

Method: The first stage involved 117 cancer survivors completing a brief screening tool evaluating fatigue, pain, depression and anxiety. The second stage comprised 33 participants who had completed the screening tool. Group comparisons were conducted between those experiencing higher levels of cancer pain and/or CRF interference and those with lower levels of cancer pain and CRF, on levels of distress, quality of life, FCR, mental defeat and health-related beliefs.

Results: The screening tool was effective at identifying physical and psychological symptoms known to be present amongst many cancer survivors and was useful in prospectively predicting quality of life and FCR. In the second stage, participants experiencing higher levels of cancer pain and/or CRF interference had significantly higher levels of psychological distress and poorer quality of life, in comparison to those with lower levels of cancer pain and CRF interference. There were no significant group differences on any of the other measures. Mental defeat was a significant predictor of psychological distress and quality of life.

Conclusions: These results highlight the detrimental impact that the experience of physical symptoms can have on cancer survivors. Findings suggest that the brief screening tool could be used clinically to provide earlier detection of cancer survivors who may be in need of psychological support.

Critical Review of the Literature

The risk factors and functions of non-suicidal self-injury (NSSI) within eating disorders: A systematic review with narrative synthesis

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Target Journal: European Eating Disorder Review
This journal has been chosen as it publishes original reviews and research that have implications for the care, treatment and clinical management of eating disorders.

Introduction

Non-suicidal self-injury (NSSI) is the direct and deliberate destruction of one's bodily tissue without suicidal intent (Washburn, Potthoff, Juzwin, & Styer, 2015). Such behaviours include cutting, burning, biting, scratching and hitting oneself but exclude socially sanctioned bodily modifications such as tattooing and piercing (Franklin & Nock, 2016).

Lifetime prevalence for NSSI has been estimated at 5.9%, with an average onset of 16 years (Klonsky, 2011). Research has shown comparable prevalence rates for NSSI in adolescent samples across numerous countries and cultures (Muehlenkamp, Claes, Havertape, & Plener, 2012). With regards to gender differences, prevalence rates of NSSI for men and women are similar, although women have been found to have an earlier age of onset (Andover, Primack, Gibb, & Pepper, 2010). Females report more cutting and scratching behaviours in comparison to males who report engaging in hitting and burning methods (Sornberger, Heath, Toste, & McLouth, 2012).

There has been discussion and disagreement in the literature regarding the distinction of NSSI from suicidal behaviour, with regards to the extent of suicidal intention involved in a self-injurious act. Some authors have contested that NSSI should be a distinct diagnosis (Kapur, Cooper, Connor, & Hawton, 2013) whilst others have suggested that NSSI and suicidal self-injury (SSI) exist on a continuum (Orlando, Broman-Fulks, Whitlock, Curtin, & Michael, 2015). Terminology used has also reflected the lack of consensus within the field, with phrases such as 'parasuicide' and 'deliberate self-harm' being used to describe both acts of self-injury with suicidal intent and those without (Muehlenkamp et al., 2012; Nock, 2012).

In the fifth edition of the Diagnostic Statistical Manual (DSM-V), NSSI has been recognised as a distinct condition but is defined as requiring further research before it can be considered as an official diagnosis (APA, 2013). It was previously captured only as a symptom of borderline personality disorder (BPD; APA, 2000) but it has been argued that this does not reflect the nature of NSSI accurately. To give a diagnosis of BPD to a young adolescent engaging in NSSI may be deemed inappropriate and even unethical, as it is a period when personality may still be developing (Wilkinson, 2013). The occurrence of NSSI has been recognised in other clinical presentations including depression, generalized anxiety disorder and substance misuse, (Nock, Joiner, Gordon, Lloyd-

Richardson, & Prinstein, 2006) and within non clinical populations (Lloyd-Richardson, Perrine, Dierker, & Kelley, 2007).

An integrated theoretical model of the development and maintenance of NSSI (Nock, 2009)

NSSI is a clinically important behaviour that can have several harmful consequences for individuals engaging in it, including the experience of powerful emotions such as guilt and shame and negative reactions from others (Wilkinson, 2013). It poses a physical risk as habituation to self-injuring behaviours may lead to increased severity of injuries and an underestimation of the lethality of these acts (Muehlenkamp & Kerr, 2010).

A growing body of literature has attempted to understand the characteristics, risk factors and functions of NSSI to improve clinical assessment, treatment and prevention. The identification of psychosocial characteristics of NSSI, including higher ratings of impulsivity, depression and suicidal thoughts, has helped to classify people who may be at a higher risk for self-injuring, yet fails to increase understanding of *why* people engage in these behaviours (Bentley, Nock, & Barlow, 2014; Nock & Prinstein, 2004).

A four-function model (FFM; Nock & Prinstein, 2004) proposed a functional approach, whereby behaviours are believed to be a consequence of events that have preceded and followed them. In this model, NSSI is maintained by four reinforcement processes: (1) Intrapersonal-negative (automatic) reinforcement, in which behaviour is followed by an immediate decrease in internal aversive thoughts or feelings; (2) Intrapersonal-positive (automatic) reinforcement, in which behaviour generates internal positive thoughts or feelings; (3) Interpersonal-negative (social) reinforcement, whereby NSSI serves to facilitate escape from undesired social situations; (4) Interpersonal-positive (social) reinforcement, in which NSSI is followed by an increase in a desired social situation (e.g. attention). This model advanced upon previous theories with its wider consideration for the social function of engaging in NSSI, in addition to the function of affect regulation (Bentley et al., 2014). Each of the four functions has been found to have moderate to high internal consistency, with over half of the sample (52.9%) in Nock and Prinstein's study (2004) endorsing intrapersonal-negative reinforcement (*'to stop bad feelings')* as a primary function for engaging in NSSI.

The FFM was incorporated into the Integrated Theoretical Model of the Development and Maintenance of NSSI (ITM; Nock, 2009), which includes general and specific vulnerability factors that increase the risk of individuals engaging in self-injury. General factors include an individual's environment and neurobiology, such as experiencing abuse or neglect in childhood or having an increased stress response. These factors are not exclusive to self-injury but are thought to lead to emotion dysregulation, poor behavioural/cognitive control and impulsivity, which in turn increase the likelihood of an individual using self-injury to regulate these difficulties.

Specific vulnerability factors include self-punishment, social learning (influence of peers), pragmatism (viewing self-injury as a rapid, effective act), implicit identification (identifying oneself as a self-injurer), social signalling (a way to elicit help) and pain analgesia (experiencing little or no pain during self-injury). These factors serve the primary function of regulation and can explain the maintenance of NSSI and an individual's decision to engage in this behaviour over an alternative. Only one study has examined the model in its entirety, using a mixed-methods design, finding support for all of the intrapersonal and interpersonal vulnerability factors and specific vulnerability factors, although some were more prevalent across the sample than others (Wester & McKibben, 2016).

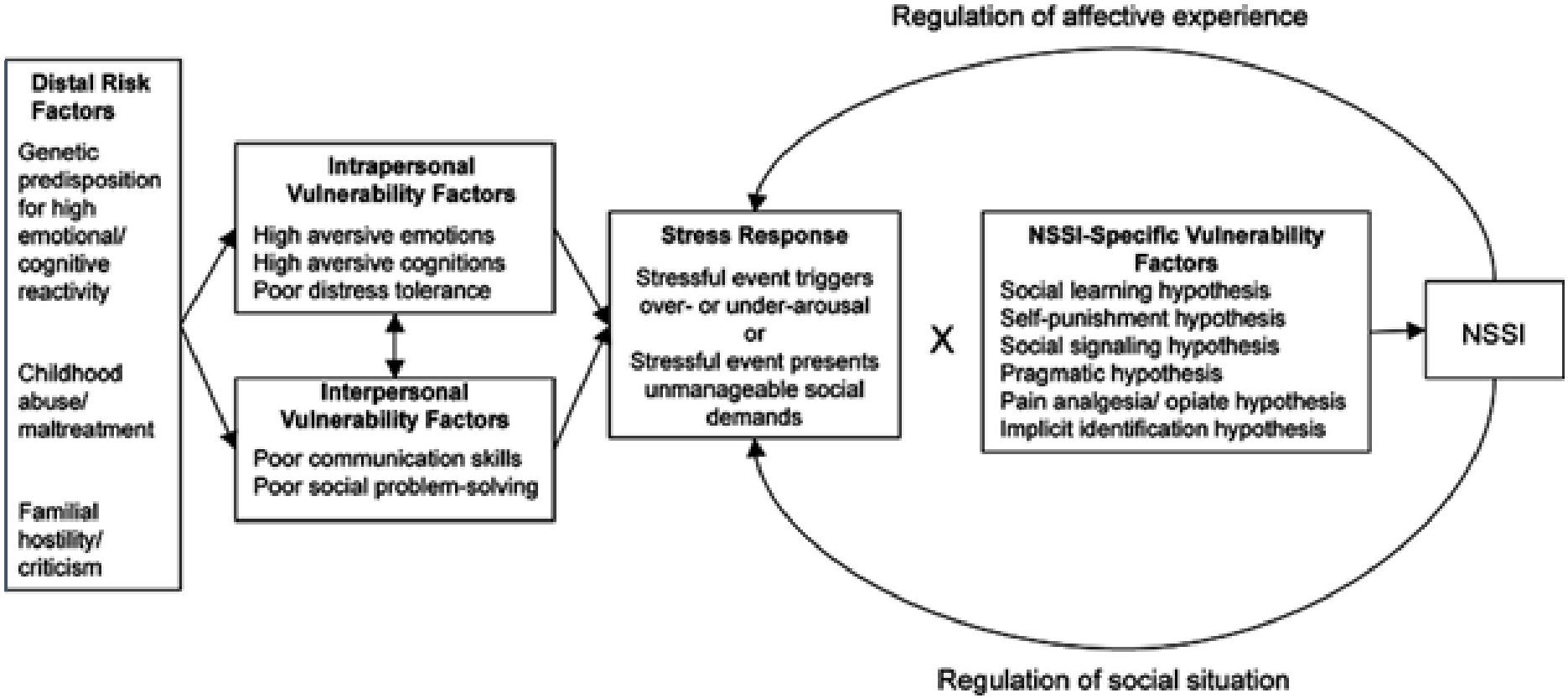

Figure 1.1 Nock's Integrated Theoretical Model of the Development and Maintenance of NSSI

NSSI and eating disorders

NSSI has been found to occur within several different clinical presentations, including eating disorders (ED). A review on the nature of this association (Svirko & Hawton, 2007) included 25 out of 62 studies which included self-injurious behaviours within ED. They reported the co-occurrence of these disorders found within two studies was 54-61%, which is indicative of a strong association. Potential factors found to contribute to this association included affect regulation, dissociation and impulsivity and the authors suggested early trauma and abuse may lead to the development of such factors. However, it should be noted that the majority of studies in this review were literature reviews or did not actually include the co-occurrence of ED and NSSI.

Eating-disordered behaviours and methods of weight control, such as purging and laxative abuse, are classed as indirect ways of mistreating or abusing one's body, due to their potential to cause marked and lasting physical change (Hooley & Germain, 2014). Discussions have focused on whether indirect self-injurious behaviours should be conceptualised as being on a continuum with NSSI, rather than as a separate condition. An investigation into this found many similarities (e.g. depressive symptoms, impulsivity) between individuals who engaged in NSSI and those who engaged in indirect self-injury only (Germain & Hooley, 2012). However, those who engaged in NSSI were found to have higher levels of self-criticism and were at a greater risk of attempting suicide. On the basis of these results, it was concluded that NSSI should remain a distinct condition rather than being viewed as interchangeable with indirect self-injury, for fear that individuals at high-risk of harm and suicide may not be identified.

A recent review explored the association of suicide and self-injury in eating disorders, including anorexia nervosa (AN), bulimia nervosa (BN) and binge eating disorder (BED; Kostro, Lerman, & Attia, 2014). Studies in this review included both clinical and community samples and ranged from sample sizes of less than one hundred up to tens of thousands. The authors reported higher rates of suicidal behaviour were more often associated with AN, whilst NSSI co-occurred frequently with eating disorders that included bingeing or purging behaviours, particularly within adolescents who engaged in cutting, burning, scratching and bruising.

Aims of the current review

There has been increased research and clinical attention towards NSSI in a bid to understand its aetiology, development and maintenance. NSSI is highly prevalent in ED and has been found to be associated with attempted suicide within this population, reflecting its clinical importance (Cucchi et al., 2016).

A number of reviews have explored the prevalence and correlates of NSSI, suicidality and different ED presentations (Cucchi et al., 2016; Kostro et al., 2014; Svirko & Hawton, 2007). However, there has not been a review conducted which has examined the risk factors and functions of NSSI within ED, suggesting that such a review could be timely.

The current review sought to provide a critical evaluation, using Nock's (2009) ITM to synthesise findings and to explore whether the risk factors and functions outlined in this model could translate across different ED presentations.

Research questions

The following research questions were considered:

1. What risk factors for NSSI have been identified in studies of people with ED?
2. What are the functions of NSSI that have been identified in studies of people with ED?
3. How do the risk factors and functions identified for NSSI in studies of people with ED fit with Nock's ITM?

Method

Search strategy

Electronic literature databases PsychINFO, PubMed and Web of Science were searched systematically to identify all papers that were on the topic of both NSSI and ED. The lead author conducted the searches in July 2016. Each search used the following combination of key words: "Non-suicidal self-injury"/ self-injur*/self-cut*/self-harm*/self-mut*/self-destr* AND Eating disorder*/"disordered eating"/eating patholog*/anorexi*/bulimi*/purg*/bing*. Reference sections of included studies and literature reviews were examined to detect any further relevant

papers. There were no date restrictions applied as the evidence base in this area is limited.

Study selection

The process of searching for and selecting studies is shown in Figure 1.2. The initial search of three databases identified 346 records, of which 244 were duplicates. Screening of the titles and abstracts identified a further 29 records which met the exclusion criteria and these were also removed. To conduct as comprehensive a search as possible of these remaining titles and abstracts, they were subject to a key word search to identify records which specifically assessed risk factors and/or functions (Table 1.1). Previous literature related to risk factors in NSSI only (Fox et al., 2015) and functions of problematic behaviour, including NSSI (Gratz, 2003; Hanley, Iwata, & McCord, 2003), was consulted to develop a wide range of search terms. 46 records were excluded from the search of risk factor key words and 44 records were excluded from the search of function key words. The remaining full-text articles were screened for relevance and in accordance with the inclusion criteria.

Table 1.1
Risk factor and function key word search terms

Risk Factors	**Function**
Risk, longitudinal, predict*, prospective*, future*	*Function, functional analysis, analysis, behavioural assessment* (English UK and US spelling), *antecedent, consequence, purpose, trigger, motivat*, reinforc*, automatic*, preced*, intent*

Inclusion criteria.

These criteria were developed in accordance with previous relevant literature in the field and were used to increase rigour and provide a comprehensive review of the literature. For all articles: (1) primary studies explicitly measuring risk factors and/or functions of NSSI in people with ED, using methods of measurement that directly investigate these factors; (2) participants with an ED diagnosis confirmed either clinically or by the research team in accordance with DSM and/or International Classification of Diseases (ICD); (3) NSSI clearly defined as deliberate physical injury

to the self only, *without* suicidal intent. Additionally, for articles related to risk factors; (4) studies investigating causal risk factors using a longitudinal design. Studies could include either clinical or community samples, in accordance with meeting the above criteria of participants meeting a DSM/ICD classification of ED diagnosis. There were no restrictions placed on the demographic characteristics of participants (e.g. age, gender, race).

Exclusion criteria.

As stated above, articles were first excluded if they were written in a language other than English and were not published in peer-reviewed journals. Reviews, book chapters and dissertations were excluded. Papers identified from the risk factor/function key word search were examined and excluded if the word identified had been used in a different context. Remaining studies were excluded if NSSI was conceptualised as being interchangeable with behaviours that had suicidal intent and if it was classified only as a symptom of another psychiatric disorder (e.g. BPD).

Data extraction.

A table was created to record data extracted from identified studies. Data extracted captured general information about the study (e.g. author, year of publication), sample and study characteristics (e.g. gender, age, methodology), specific ED and NSSI characteristics (e.g. measurement) and results.

Quality appraisal

Instruments used to appraise the quality of non-randomised studies were subject to a systematic review (Deeks et al., 2003) and it was suggested that only 6 out of 182 tools could potentially be useful. One of the tools assessed to be most useful included the Newcastle Ottawa Scale (NOS; Wells et al., 2008). The NOS was originally devised to assess the quality of case-control and cohort studies, although both Deeks et al. (2003) and the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011) advise that it should be adapted accordingly for each review conducted. As this review comprised cohort and cross-sectional designs, the NOS scale was adapted using existing appraisal checklists for guidance.

The following criteria was used to appraise the quality of studies: (1) Selection (representativeness of the sample, use of a control group, valid measures for assessing outcome of interest); (2) Confounding factors (whether these were controlled for); (3) Outcome (how outcomes of interest were assessed e.g. repeated measurements, self-report, blind assessment; description and appropriateness of statistical tests used). For criterion fulfilled, the study was awarded a point of one and for those not fulfilled there were zero points awarded. The only exception to this was related to outcome measurements, where an additional point was awarded to studies employing methodology that increased reliability and validity (e.g. blind assessment, Ecological Momentary Assessment (EMA)). The total quality score that studies could be awarded was 12. The results of the quality appraisal are displayed in Table 1.4.

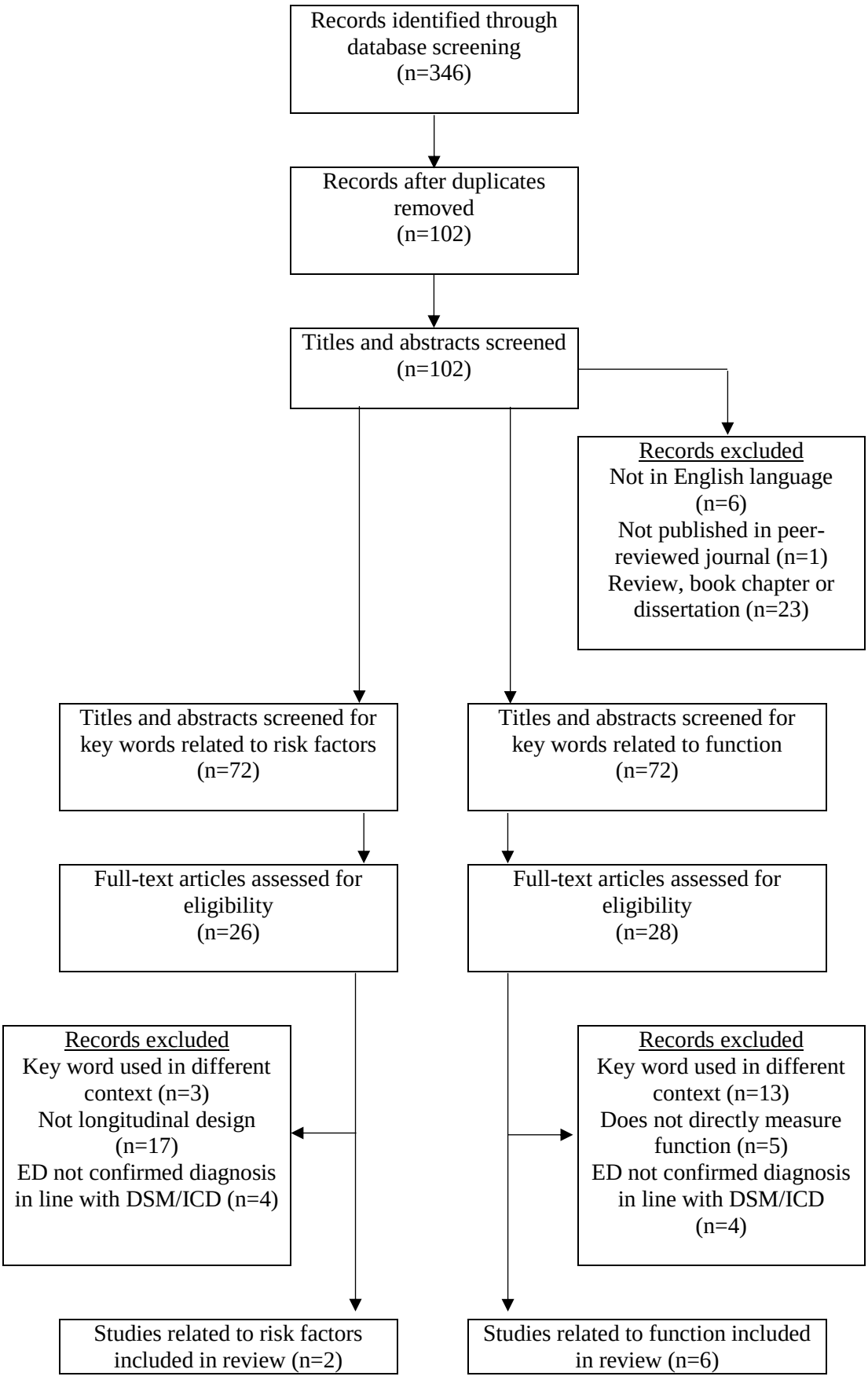

Figure 1.2 Flow chart of study selection

Results

Two papers were identified as measuring risk factors for NSSI in people with ED and six papers identified as investigating the function of NSSI in people with ED. None of the studies were relevant for both risk factors and function. However, two of the identified studies used the same community sample; one study assessing risk and one assessing function. They are both included as their research questions and methodologies are distinctly adapted to measure risk factors and function separately. Four of the studies investigating function have the same lead author, however all are included as they use different samples.

Across the eight papers identified, there were 666 unique participants, ranging in age from 12-55 years (of those reported). All participants had an ED diagnosis, with the majority having a diagnosed subtype of BN (47%) or AN (41%). The approximate prevalence of reported NSSI across participants was 38%. Further details of the sample, methodology and results of each paper that met with inclusion criteria are outlined in Tables 1.2 and 1.3.

Question 1: What risk factors for NSSI have been identified in studies of people with ED?

Quality appraisal and limitations within literature.

Both studies identified were deemed to be of good quality with Anestis et al. (2012) scoring 9/12 and Vansteelandt et al. (2013) scoring 7/12. The strengths of both studies were the representativeness of samples, use of EMA and controlling for confounding factors (e.g. ED diagnosis and other psychiatric disorders). The findings of Anestis et al. (2012) were slightly weakened due to the fact it does not report how many participants engaged in NSSI and how many did not. The slightly lower score awarded to Vansteelandt et al. (2013) resulted from the use of a non-validated questionnaire to measure the risk factor being assessed and from capturing the presence/absence of NSSI from medical records only, without additional self-report during the study period. A disadvantage of using retrospective data is the limited control over data collection, as there may have been inaccuracies in reporting.

Sample characteristics.

The two studies had a combined total of 185 participants. Participants in Anestis et al. (2012) were drawn from a community sample, with 51.1% identified as full-time students and 96.9% as Caucasian. Participants in Vansteelandt et al. (2013) were drawn from a clinical sample of inpatients admitted to a specialist ED unit.

Eating disorder characteristics and measures.

Anestis et al. (2012) aimed to recruit participants with a diagnosis of BN and reporting kappa ratings of inter-rater reliability in diagnosis as 1.00. Vansteelandt et al. (2013) recruited participants with confirmed diagnoses of AN (of both restricting and binge-purging subtypes) and BN.

NSSI characteristics and measures.

Neither study used a validated tool to measure NSSI. Anestis et al. (2012) created a NSSI variable by summing the number of times a participant endorsed self-injurious behaviours of cutting, burning, head banging and repeated hitting. However, the study does not report how many participants in the sample reported engaging in NSSI. In Vansteelandt et al. (2013), only 16 participants were recorded as having ever engaged in NSSI. No other NSSI characteristics were recorded.

Design.

Both studies employed a longitudinal design using EMA to capture participants' behaviour and emotional experiences in current time. The studies were both conducted over a discrete period of between one and two weeks, with data collection at several time-points each day. Vansteelandt et al. (2013) programmed signals according to a stratified random interval time-series, ensuring that participants could not anticipate them. Anestis et al. (2012) directed readers to another of their published papers for a description of the procedure used (Anestis et al., 2010). From this, it appeared participants provided data in response to six semi-random signals per day, after engaging in self-destructive behaviours (e.g. NSSI/bingeing/purging) and at the end of each day.

Table 1.2
Risk factor study characteristics

Study	Method	Sample	ED measure and diagnosis	Measure of NSSI and behaviours assessed	Risk factor assessed	Length of study (months)	Results
Anestis et al. (2012) USA Quality score: 9/12	*Design:* Longitudinal design using EMA *Setting:* Community	*Sample:* n=127 *Age*: range=18-55 years, Mean=25.34, SD=7.71 *Gender:* All female	*Measure:* SCID for DSM-IV Axis 1 Disorders *Diagnosis:* All BN diagnosis	*Measure:* Self-destructive behaviour checklist, summing self-reported NSSI episodes during study duration *Behaviour*: cutting, burning, repeating hitting, head banging *No. of NSSI participants:* not reported *Frequency of NSSI behaviours:* not reported	Interaction between affective liability and lifetime previous suicide attempts	0.46 (2 weeks)	• Higher levels of self-reported affective lability and number of lifetime suicide attempts interact to predict greater number of NSSI episodes during study duration (t=4.01, $p < 0.001$, sr=0.31, f^2=0.48)

Vansteelandt et al. (2013) Belgium Quality score: 7/12	*Design:* Longitudinal design using EMA *Setting:* Clinical inpatient	*Sample:* n=58 *Age*: range=13.8-38.5 years, mean=21.3, SD=5.6 *Gender:* All female	*Measure:* SCID for DSM-IV Axis 1 Disorders (Dutch version) *Diagnosis:* 21 AN-RT; 17 AN-BPT; 20 BN *BMI:* AN-RT mean=14.6, SD = 1.4, range=12.1-16.8; AN-BPT mean=15.9, SD = 1.2, range=13.6-17.8; BN mean=21.1, SD = 2.6, range=18.3-28	*Measure:* Absence/presence of lifetime NSSI noted in medical records (dichotomous yes/no) *Behaviour:* not known *No. of NSSI participants:* 16 with NSSI, 42 without	Affective variability (valence and activation)	0.23 (1 week)	• Participants with NSSI have higher mean for variability in activation, but not for valence, than those without NSSI (mean=2.82, SD=0.78, F(1,56)=7.46, p=0.008) • Variability in activation is a significant predictor of lifetime NSSI (odds ratio=5.71, p=0.01)

Note: ED=eating disorder; NSSI=non-suicidal self-injury; EMA=Ecological Momentary Assessment; SD=standard deviation; SCID=structured clinical interview; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; BN=bulimia nervosa; AN-RT=anorexia nervosa restrictive type; AN-BPT=anorexia nervosa binge-purge type

Risk factors assessed and results found.

Both studies investigated the role of affect as a potential risk factor for NSSI. Anestis et al. (2012) examined whether an individual's previous suicidal behaviours interacted with self-reported affective lability to predict the number of times they engaged in NSSI behaviours during the study follow-up period. At baseline, the authors assessed the number of lifetime suicidal gestures or attempts each participant had made by way of a diagnostic semi-structured interview for BPD symptoms. Affective lability is a term used to describe rapid shifts in the intensity and valence (e.g. positive or negative affect) of one's emotional expression and this was also measured at baseline using the affective lability subscale of the dimensional assessment of personality pathology-basic questionnaire (DAPP-BQ). The authors commented on the reliability and internal consistency of both of these measures. In this study, EMA recorded numbers of dysfunctional behaviours participants engaged in (e.g. NSSI) and intensity of negative affect during the day. Results supported their hypothesis that higher levels of affective lability and the presence of previous suicidal behaviour would interact to predict higher rates of NSSI behaviours.

Vansteelandt et al. (2013) investigated whether affective variability (valence and activation e.g. level of arousal) predicted the number of lifetime NSSI episodes that an individual had engaged in. EMA measured affective variability using an unvalidated questionnaire developed specifically for the study. These scores were predictor variables and a logistic regression model analysed their effect on the presence/absence of lifetime NSSI. They found that individuals with an ED diagnosis and NSSI showed higher levels of variability in affective activation than those without NSSI, but that variability in valence and mean levels of both activation and valence did not vary significantly between the two groups. For those who engaged in NSSI, results also showed that variability in affective activation predicted lifetime NSSI whilst variation in affective valence did not.

Question 2. What are the functions of NSSI that have been identified in studies of people with ED?

Quality appraisal and limitations within literature.

Four of the six studies were deemed as being of good quality with scores of eight or higher, out of twelve. The other two studies also scored fairly well with one study just

below 50% (Claes, Klonsky, Muehlenkamp, Kuppens, & Vandereycken, 2010) and the other at 50% (Itzhaky, Shahar, Stein, & Fennig, 2016). The studies scoring highly demonstrated representativeness in their samples, controlled for several confounding factors (e.g. age, gender, ED diagnosis), used self-reported outcomes and reported the results of appropriate statistical analyses. Muehlenkamp et al. (2009) was awarded an additional point for the use of EMA in addition to self-reported outcomes. All studies used validated measures to assess functions of NSSI.

A control group would not have been necessary for analysing research questions related to the functions of NSSI only. However, a point was awarded to studies that included a control group when investigating other primary research questions, as this strengthened their findings.

The primary reason for two studies scoring slightly less in the quality appraisal was caused by not controlling for as many confounding factors as others did.

Sample characteristics.

The sample size of all six papers ranged from 51 to 177 participants. Four studies appeared to include adult samples, although only one of these studies (Muehlenkamp et al., 2009) stated exclusion criteria for any participant under the age of 18 years. One study explicitly used an adolescent population (Itzhaky et al., 2016) and another used a mixed population of adolescents and adults (Claes, Soenens, Vansteenkiste, & Vandereycken, 2012). Five of the six studies were made up of an entirely female sample although the sixth only had four males (Itzhaky et al., 2016). One study used a community sample (Muehlenkamp et al., 2009) whilst the other studies used clinical samples; both inpatient and outpatient.

Eating disorder characteristics and measures.

Muehlenkamp et al. (2009) recruited participants from the community with a BN diagnosis only. All of the other studies recruited participants with a range of diagnoses, including two subtypes of AN (restrictive and binge-purge), two subtypes of BN (purge and non-purge), binge-eating disorder (BED) and eating disorder not otherwise stated (EDNOS). Two studies reported mean BMI levels (Claes, Norré, Van Assche, & Bijttebier, 2014; Muehlenkamp et al., 2009).

NSSI characteristics and measures.

Four of the studies measured NSSI using the Self-Injury Questionnaire – Treatment Related (SIQ-TR; (Claes & Vandereycken, 2007) which was developed and validated by the lead author in each of these studies. The SIQ-TR primarily gathers data for five self-injurious behaviours (scratching until bleeding, bruising, cutting, biting and burning) but also allows individuals to answer according to other NSSI acts they may engage in. It assesses when the individual last engaged in NSSI behaviour, frequency, pain felt, affect before and after, premeditation and function/motivation. One study used the Functional Assessment of Self-Mutilation (FASM; Lloyd, Kelley, & Hope, 1997) which assesses methods used, frequency and functions of self-injury. The sixth study (Muehlenkamp et al., 2009) brought together items from several scales to create a checklist of self-injurious behaviours for participants to indicate those they had engaged in. This checklist did not capture frequency or function of behaviours.

Design.

Five studies employed a cross-sectional study design using questionnaire and quantitative data from interviews. One study was longitudinal (Muehlenkamp et al., 2009), using EMA to capture real-time emotional states before and after acts of NSSI over a two-week period.

Table 1.3
Function study characteristics

Study	Method	Sample	ED measure and diagnosis	Measure of NSSI and behaviours assessed	Results
Muehlenkamp et al. (2009) USA Quality score: 9/12	*Design:* Longitudinal using EMA *Setting:* Community	*Sample:* n=131 *Age:* mean=25.3, SD=7.6 *Gender:* All female	*Measure:* SCID for DSM-IV Axis I Disorders, Patient Edition – Eating Disorder Module *Diagnosis:* All BN *BMI:* mean=23.8; SD=5.25	*Measure:* A self-injurious behaviour checklist *No. of NSSI participants:* 14.5% (n=19) NSSI *Behaviours:* Cutting, scratching, burning, hitting, head banging	• Prior to acts of NSSI, negative affect significantly increased (t(212)=2.94, p< 0.01), whilst positive affect significantly decreased (t(212)=-3.20, p< 0.01) • After acts of NSSI, positive affect significantly increased, whilst levels of negative affect remained unchanged.
Claes et al. (2010) Belgium Quality score: 5/12	*Design:* Cross-sectional *Setting:* Clinical; inpatient eating disorder facility	*Sample:* n=177 *Age*: Mean=24.93, SD=7.62 *Gender:* All female	*Measure:* Diagnostic interview (DSM-IV) *Diagnosis:* 48 AN-RT, 34 AN-BP, 17 BN-NP, 55 BN-P, 19 EDNOS, 4 N/A	*Measure:* SIQ-TR *No. of NSSI participants:* 43.5% (n=77) NSSI in past year; 27.7% (n=49) in past month or week *NSSI behaviours:* in past week or month, 18.1% (n=32) severe scratching,	• 49 participants who had engaged in NSSI in past week or month were focus of analysis • Functions endorsed for NSSI: '*to avoid or suppress negative feelings'* burning (100%), cutting (76.9%), severe scratching (68.8%); '*to punish oneself'* bruising (93.8%). '*To get attention from others'* and

				14.7% (n=26) cutting; 9% (n=16) bruising, 2.8% (n=5) burning.	'*to show others how strong I am'* rarely or never mentioned • Positive valence-low arousal affect state (e.g. relieved) showed substantial increase from before to after acts of NSSI. Negative valence-high arousal showed substantial decrease from before to after acts of NSSI (e.g. anger at self and/or others) • Results show positive associations (but not significant) between increase of positive affect and number of functions endorsed.
Claes et al. (2012) Belgium Quality score: 9/12	*Design:* Cross-sectional *Setting:* Clinical; specialised inpatient eating disorder unit	*Sample:* n=95 *Age:* range=14-42, mean=21.5, SD=6.23 *Gender:* All female	*Measure:* Diagnostic interview (DSM-IV) and questionnaire (EDES) *Diagnosis:* 44 AN-RT, 12 AN-BP, 28 BN, 11 EDNOS	*Measure:* SIQ-TR *No. of NSSI participants:* 38.9% (n=37) NSSI; 61.1% (n=58) non-NSSI *Behaviours:* 21.1% (n=20) cutting, 20% (n=19) hair pulling, 14.7% (n=14) scratching, 12.6% (n=12)	• Participants with NSSI scored significantly higher on levels of evaluative concerns perfectionism (ECP; $F=5.58$, $p<0.05$) and perceived parental criticism (PPC; $F=5.62$, $p<0.05$) than those without. • Three functions of interest in study (self-punishment, self-torturing and cry-for-help) all showed significantly positive

				bruising, 4.2% (n=4) burning	relationships with ECP (β=0.3, 0.3, 0.36 respectively, p<0.05-0.01); cry-for-help function significantly negative relationship with PPC (β =-0.29, p<0.01)
Claes et al. (2014) Belgium Quality score: 8/12	*Design:* Cross-sectional *Setting:* Clinical; outpatient private practice	*Sample:* n=51 *Age:* mean=26.33, SD=9.03 *Gender:* All female	*Measure:* Eating disorder section of DSM-IV and EDI-2 *Diagnosis:* 19 AN-R, 8 AN-BP, 19 BN, 5 EDNOS *BMI:* AN-R, mean=17.23, SD = 1.74; participants with binge/purging behaviours (AN-BP, BN, EDNOS), mean=22.84, SD = 6.76	*Measure:* SIQ-TR *No. of NSSI participants:* 33% (n=17) NSSI (lifetime) *Behaviours:* 19.6% severe cutting, 19.6% hitting, 17.6% superficial cutting, 13.7% head banging, 9.8% scratching, 5.9% burning	• Four factors were found which explained 77.63% of variance in NSSI functions assessed: (1) α=.72, 5 items, External-Positive Reinforcement (increase of positive attention from others after NSSI); (2) α=.75, 2 items, External-Negative Reinforcement (avoid social activities); (3) α =.93, 2 items, Internal-Negative Reinforcement (avoid/suppress negative feelings); (4) α =.66, Three items, self-

					punishment, avoidance/escape of suicidal thoughts, numb state (not labelled) • Factors 1 and 2 not correlated with temperament, Factor 3 positively correlated with Negative Affectivity (r=.51, p<0.05), negatively correlated with Positive Affectivity/Extraversion (r=-.62, p<0.05). Factor 4 negatively correlated with Effortful Control (r=-.0.68, p<0.01)
Claes et al. (2015) Belgium Quality score: 9/12	*Design:* Cross-sectional *Setting:* Clinical; inpatient and outpatient	*Sample:* n=99 *Age:* mean=27.75, SD=9.26 *Gender:* All female	*Measure:* Diagnostic interview (DSM-IV) and EDI-2 *Diagnosis:* 20 AN-R, 16 AN-BP, 41 BN, 22 BED	*Measure:* SIQ-TR *No. of NSSI participants:* 58.5% (n=56) NSSI *Behaviours:* 39.4% superficial cutting, 39.4% severe cutting, 37.4% scratching, 32.3% bruising/hitting, 28.3% head banging, 19.2% burning, 18.2% picking	• Most strongly endorsed functions for NSSI were '*to avoid or suppress negative feelings'* (M= 4.21, SD = 1.07) and '*to punish myself*' (M= 3.93, SD = 1.28) • Participants with NSSI scored significantly higher for identity confusion (*F*(1,90)=7.45, p<0.01) and significantly lower for identity synthesis than participants without NSSI (*F*(1,90)=18.79, p<0.001)

					• Three factors were found which explained 42% of variance in NSSI functions assessed: (1) α=.76, 6 items, automatic positive reinforcement (obtaining desired internal state); (2) α=.72, 6 items, automatic negative reinforcement (reduce unwanted internal state); (3) α=.82, 2 items, social negative reinforcement (escape unwanted social situations/demands) • Automatic negative reinforcement function positively related to identity confusion (r=.34, p=sig.) and negatively related to identity synthesis (r=-.34, p=sig.)
Itzhaky et al. (2016) **Study 2** Israel Quality score: 6/12	*Design:* Cross-sectional *Setting:* Clinical; inpatient eating	*Sample:* n=55 *Age:* range=12-18.5, mean=15.7, SD=1.81 *Gender:* 51 female, 4 male	*Measure:* SCID for DSM-IV and the Eating Disorder Family History Interview *Diagnosis:* 66% AN, 7% BN, 27% EDNOS	*Measure:* FASM *No. of NSSI participants:* 62% (n=34) NSSI at least twice in past year *Behaviours:* 23% minor (hitting, biting, pulling	• Functions endorsed by participants for NSSI: 85% automatic negative motivation, 79% automatic positive reason, 50% social negative motivation and 82% social positive motivation.

	disorder hospitals			hair); 21% moderate/severe (erasing skin, burning, cutting); 56% both	• Dependency predicted higher levels of automatic positive motivation only under low levels of self-criticism ($p < .05$, 95% CI = 0.61– 5.73). • Self-criticism predicted higher levels of automatic positive motivation only under low levels of dependency ($p < .01$, 95% CI = 0.86–4.79). • There were no other significant effects of dependency and self-criticism on the other functions found.

Note: ED=eating disorder; NSSI=non-suicidal self-injury; EMA=Ecological Momentary Assessment; SD=standard deviation; SCID=structured clinical interview; DSM-IV=Diagnostic and Statistical Manual of Mental Disorders, 4th edition; BN=bulimia nervosa; AN-RT=anorexia nervosa restrictive type; AN-BPT=anorexia nervosa binge-purge type; BN-NP=bulimia nervosa non-purging; BN-P=bulimia nervosa purging; EDNOS=eating disorder not otherwise specified; N/A=not available; BED=binge eating disorder; EDES=eating disorder examination; SIQ-TR=self-injury questionnaire-treatment related; EDI-2=eating disorder inventory-2; FASM=functional assessment of self-mutilation; BMI=body mass index

Functions assessed and results found.

Many of the identified studies investigated functions of NSSI as a secondary research question. This section will summarise only the research questions and findings related to function.

Claes, Klonsky, Muehlenkamp, Kuppens, & Vandereycken (2010) aimed to assess similarities and differences in self-reported functions across various types of NSSI and to specifically explore an affect regulation function by examining changes in affect valence and arousal before/after NSSI. The authors concluded that people with an ED diagnosis may engage in NSSI to regulate emotions. Similar conclusions were reached by Muehlenkamp et al. (2009), through the use of EMA to assess prospective real-time emotional states before and after acts of NSSI.

Claes et al. (2014) sought to investigate dimensions of temperament and the associations and interactions they may have with NSSI and its functions in people with an ED diagnosis. Temperament was assessed using a validated tool which measured reactive (negative affectivity, extraversion/agency) and regulative (effortful control e.g. one's ability to self-regulate emotional experience and expression) aspects of temperament. From their findings, the authors suggested that individuals who respond in a negative reactive way to stressful situations may not be able to control and regulate this response, turning to NSSI behaviours to achieve this instead.

Claes et al. (2012) investigated whether perfectionism and perceived parental criticism (PPC) was related to three particular functions of NSSI: self-punishment, self-torturing and cry-for-help. Perfectionism was divided into two types: personal standards perfectionism (PSP) and evaluative concerns perfectionism (ECP). PSP involves an individual setting high personal standards, although this can include positive goal setting. ECP relates to concerns about making mistakes when attempting to achieve high personal standards and can involve negative evaluations of the self, leading to self-criticism. The authors concluded that ED patients with ECP may punish themselves through NSSI due to perceived failings in the standards they uphold for themselves, with PPC acting as a potential risk factor for the development of self-criticism.

Itzhaky et al. (2016) cited findings from previous literature that self-criticism and dependency (being more dependent on others for emotional regulation) are associated

with ED. They set out to investigate the role of these two traits in NSSI in adolescents with an ED diagnosis and whether these traits would interact to predict individual motivation for NSSI, through the use of validated tools. A two-way interaction of dependency and self-criticism (e.g. high dependency with low self-criticism or high self-criticism with low dependency) was found suggesting that individuals may be motivated to achieve a desired physiological state through NSSI in order to either feel comfort (dependency) or to punish themselves (self-criticism).

Claes et al. (2015) investigated how identity formation is related to both ED and NSSI, using validated measures. A specific research question explored the association of problems in formation with characteristics of NSSI, including function. Identity formation (Erikson, 1994) is the process in which an individual successfully achieves greater identity synthesis over confusion, thus developing an internal feeling of having a solid identity that is continuous across time and context. Identity confusion leads to individuals having a disorganised sense of self with uncertainty about themselves or their role in society. The results suggested that individuals with ED may engage in NSSI in a bid to establish a pseudo-identity as a self-injurer, if they are experiencing difficulties in forming a cohesive sense of self.

Table 1.4
Quality Appraisal

Study	Selection				Controlling for confounding factors					Outcome		
Risk	***Sample size***	***Representative sample***	***Control Group***	***Valid measure of risk factor***	***Gender***	***Age***	***ED diagnosis***	***ED severity***	***Other psychiatric diagnoses***	***Assessment of outcome***	***Statistical test***	**Score (out of 12)**
Anestis et al. (2012)	127	1; Community	0	1; DAPP-BQ affective lability, diagnostic interview for past suicide attempt	1	0	1	1	1; depression	2; additional point for EMA	1	9
Vansteelandt et al. (2013)	58	1; ED IP	1	0; EMA questionnaire developed	1	0	1	0	1; depression, BPD	1; single point for EMA	1	7
Function	***Sample size***	***Representative sample***	***Control Group***	***Valid measure of function***	***Gender***	***Age***	***ED diagnosis***	***ED severity***	***Other psychiatric diagnoses***	***Assessment of outcome***	***Statistical test***	**Score (out of 12)**
Claes et al. (2010)	177	1; ED IP	0	1; SIQ-TR	1	0	0	0	0	1; self-report	1	5

Claes et al. (2012)	95	1; ED IP	1	1; SIQ	1	1	1	1	0	1; self-report	1	9
Claes et al. (2014)	51	1; ED OP	1	1; SIQ-TR	1	1	1	0	0	1; self-report	1	8
Claes et al. (2015)	99	1; ED IP & OP	1	1; SIQ-TR	1	1	1	0	1; depression	1; self-report	1	9
Itzhaky et al. (2016) Study 2	55	1; ED IP	1	1; FASM	0	0	0	0	1; depression, suicidal behaviour	1; self-report	1	6
Muehlenkamp et al. (2009)	131	1; Community	1	1; PANAS	1	1	1	0	0	2; additional point for EMA	1	9

Note: ED=eating disorder; DAPP-BQ=Dimensional Assessment of Personality Pathology – Basic Questionnaire; EMA=Ecological Momentary Assessment; IP=inpatient; OP=outpatient; SIQ-TR=self-injury questionnaire-treatment related; FASM=functional assessment of self-mutilation; PANAS=positive and negative affect schedule

Question 3. How do the risk factors and functions identified for NSSI in studies of people with ED fit with Nock's ITM?

Distal risk factors.

None of the identified studies directly investigated the distal risk factors (genetic predisposition, childhood abuse, familial criticism) proposed by the ITM.

However, two studies (Claes et al. 2012; Itzhaky et al. 2016) investigating the functions of NSSI in people with ED, discussed their results in relation to risk factors. The findings of these studies suggest that perfectionism, self-criticism and PPC may be linked to the distal risk factor of familial hostility/criticism in the ITM. However, the cross-sectional design and self-reported PPC do not allow inferences to be made regarding causality.

Intrapersonal and interpersonal vulnerability factors.

The ITM suggests that distal risk factors may cause the development of intrapersonal vulnerabilities such as high emotional reactivity and an inability to manage distress. The two studies related to risk factors appear to partially fit within the intrapersonal vulnerability factor of experiencing high aversive emotions. However, they both demonstrate that there are particular aspects of affect dysregulation which increase the risk of individuals with an ED diagnosis engaging in NSSI.

Vansteelandt et al. (2013) highlighted that negative affect in itself does not predict NSSI. They suggest it is rather the variability in levels of affective arousal that is more aversive and puts an individual at higher risk of engaging in NSSI. Anestis et al. (2012) demonstrated that experiencing frequent shifts in both affect valence and intensity (high affective lability) may be aversive. In addition, it was the interaction of previous suicide attempts with affective lability that predicted NSSI in their study, whereas the ITM does not explicitly consider suicide attempts as a risk factor.

None of the identified studies reported findings related to the high aversive cognitions aspect of the intrapersonal vulnerability factors or to the interpersonal vulnerability factors outlined in the ITM.

Four function model: regulation of affective experiences (intrapersonal) and social situations (interpersonal).

Claes et al. (2014) was the only study with an explicit aim to replicate the FFM (Nock & Prinstein, 2004) and exploratory factor analysis provided support for three of the functions outlined in the model. A fourth factor was identified which included self-punishment, avoiding/escaping a numb state and suicidal thoughts. Self-punishment is captured within Nock and Prinstein's (2004) definition of intrapersonal-positive reinforcement, however, the other two items found do not. The authors argued that these additional items could refer to either intrapersonal-positive or intrapersonal-negative reinforcement depending on the needs of the individual. However, they did not load onto other factors and this fourth factor was not named. The authors concluded that they achieved a partial replication of the FFM, hence, the results also partially fit with the ITM.

Claes et al. (2015) identified intrapersonal-negative reinforcement and interpersonal-negative reinforcement but differed from Claes et al. (2014) by identifying intrapersonal-positive reinforcement as a third factor. Whilst both studies used the same questionnaire (SIQ-TR) to assess self-reported function of NSSI, Claes et al. (2015) expanded the list of motives to 18 from 14. Items that loaded onto interpersonal-positive reinforcement in Claes et al. (2014) e.g. '*to show others how strong I am'* and '*to get attention from others,'* alternatively loaded onto intrapersonal-positive reinforcement in Claes et al. (2015). In contrast, the findings of Itzhaky et al. (2016) endorsed all four functions identified by Nock & Prinstein (2004) but this may have been affected by the use of the same questionnaire (FASM; Lloyd et al., 1997) in both studies to assess function.

Three studies (Claes et al., 2010; Claes et al., 2015; Itzhaky et al., 2016) reported that the most commonly endorsed motivations for engaging in NSSI were related to the intrapersonal-negative reinforcement function. Specifically, in Claes et al. (2010) and Claes et al. (2015) this was defined as the item '*to avoid or suppress negative feelings'*. In both studies this was followed by '*to punish myself*' which is related to the intrapersonal-positive reinforcement function. In contrast to other studies, Claes et al. (2010) reported that participants rarely or never endorsed socially reinforced motives.

Muehlenkamp et al. (2009) and Claes et al. (2010) found contrasting results with the former reporting no substantial change in levels of negative affect after NSSI and the latter reporting a significant reduction in levels. Muehlenkamp et al. (2009) questioned

whether self-reported relief from negative emotions after NSSI in other studies may have been caused by significantly increased positive affect diminishing the distress felt from negative emotions. Claes et al. (2010) did acknowledge that there was a considerable level of negative affect remaining after NSSI, despite their significant findings.

The studies described above found direct evidence that NSSI can function to regulate internal emotional experiences and external social demands, in line with the interpersonal and intrapersonal reinforcing functions outlined in the ITM.

NSSI-specific vulnerability factors.

Other studies identified additional factors that are related to and influence the intrapersonal and interpersonal reinforcing functions and these were more relevant to the specific vulnerability factors outlined in the ITM. The findings of Claes et al. (2012) regarding NSSI as a function of self-punishment arising from higher levels of ECP, fits with the ITM in both the intrapersonal-positive reinforcement function and specific vulnerability factor of self-punishment. ECP was also found to be positively related to a cry-for-help function which could be similar to the specific vulnerability factor of social signalling in the ITM.

In contrast to these findings and the ITM, two studies demonstrated that there may be circumstances when individuals do not use social signalling. Claes et al. (2012) suggested that if an individual has learned that soliciting an emotional response from a caregiver could lead to a negative and aversive reaction then they may avoid others and not signal their distress. The findings of Itzhaky et al. (2016) that NSSI may function as self-punishment when dependency on others is low, could be comparable to this. If self-criticism has been theorised to develop from punishing parental figures, then self-critical individuals may become more autonomous and less dependent on others to help regulate their emotions and engage in NSSI as an alternative.

The conclusion from Claes et al. (2015) that NSSI may help those with identity confusion through the development of a pseudo-identity as a self-injurer, fits with the specific vulnerability factor of implicit identification within the ITM. Causality cannot be established due to the cross-sectional nature of the study.

The findings of Claes et al. (2014) fit with the ITM in that individuals who experience high negative reactivity may not be able to regulate their emotions in response to stress and instead turn to NSSI to suppress their negative affect. Additionally, their finding that self-punishment is associated with low effortful control could fit with the pragmatic hypothesis of the model. NSSI may be an attractive and easily accessible option to help individuals self-punish or avoid suicidal thoughts if they lack the control to effectively regulate their emotional experiences.

The studies described above found evidence for the specific vulnerability factors of self-punishment, social signalling, pragmatic and implicit identification hypotheses. However, none of the identified studies found evidence of the social learning or pain analgesia/opiate hypotheses.

Discussion

The current review sought to investigate the risk factors and functions of NSSI in people with ED diagnoses. Three key questions were addressed regarding risk factors that make people with ED diagnoses more likely to engage in NSSI, understanding the function of NSSI and whether Nock's ITM was suitable within an ED population.

With regards to risk factors for NSSI, only two studies met with the inclusion criteria. Both studies investigated how problems in specific aspects of affect regulation may make individuals with ED more vulnerable to engaging in NSSI. In particular, one found that high variability in the level of emotional arousal predicted retrospective engagement in NSSI. The other found that trait affective lability interacted with previous suicidal behaviours to predict the number of NSSI acts during the study duration. These studies and the risk factors they assessed did not fit with the distal risk factors outlined in the ITM. Instead, they are more comparable with the model's intrapersonal vulnerability factors, which includes high aversive emotions and poor distress tolerance. Nock (2009) acknowledged that the vulnerability factors outlined in the model are a risk for a range of psychiatric disorders and that when these factors are controlled for, analyses have found that childhood abuse and other psychiatric disorders are not actually related to NSSI. They suggest this indicates that NSSI is associated with other disorders due to these shared intra- and interpersonal vulnerability factors. Therefore, it appears investigating whether vulnerability factors are predictive of NSSI within individuals with an ED diagnosis, may be helpful for understanding the etiological pathway for both conditions. The findings of

the studies in the current review appear important as they demonstrate that the presence of difficulties in these specific aspects of affect regulation make some individuals more likely to engage in both ED behaviours (e.g. purging, bingeing, restricting) and self-injurious acts.

The results of this current review may reflect the difficulties of measuring risk factors and vulnerabilities for NSSI in general, not just within an ED population. A recent meta-analysis of risk factors for NSSI alone, found that risk factor magnitude was significant, yet weak (Fox et al., 2015). The three risk factors that produced the greatest effect in predicting NSSI were a prior history of NSSI, having a Cluster B diagnosis (e.g. borderline personality disorder) and hopelessness; none of which appear within the ITM.

In relation to the functions of NSSI within people with an ED diagnosis, all studies found evidence that NSSI serves as a reinforcing behaviour for individuals, whether that be internally or socially. This fits well with the ITM. In particular, results provided support for individuals primarily engaging in NSSI to reduce internal unwanted negative feelings (intrapersonal-negative reinforcement). Studies slightly differed from one another, and from the FFM, with regards to how self-reported motives for NSSI loaded onto each factor. One reason for this may be due to measurement, as four studies used the SIQ-TR which has been updated over time to include a wider range of motives which vary slightly from the FASM utilised by Nock & Prinstein (2004). Another could be that these studies measured retrospective motivations for NSSI, asking participants to recall motivations for self-injurious acts from the past year. This may have left the results open to potential confounding factors due to limitations in memory. Participants may have found it challenging to recall internal motivations for engaging in NSSI, from a time when they may have experienced difficulty in regulating their emotions.

A particularly interesting aspect of these studies was that they highlighted other factors which may interact with the reinforcing functions of NSSI. The specific vulnerability factors outlined in the ITM fit with some of the study findings related to identity confusion (implicit identification), low effortful control (pragmatic hypothesis) and ECP (self-punishment and social signalling). These findings provided a greater understanding of why people may choose to engage in NSSI alongside ED behaviours. Perfectionism, alongside self-criticism that may develop from this, appeared relevant to the co-occurrence of ED and NSSI. NSSI literature has focused on the role of impulsivity

(Hamza, Willoughby, & Heffer, 2015) without considering the more overcontrolled aspects of personality, such as perfectionism. In contrast, ED literature has demonstrated an association between perfectionism and eating disorders (Wade, O'Shea, & Shafran, 2016). When this is considered alongside the findings of Claes et al. (2012) and Itzhaky et al. (2016) it may be that perfectionism and self-criticism would be an interesting avenue of further research within both NSSI and ED.

The risk factors and functions identified in the studies of NSSI within ED fit with several aspects of the ITM, such as the intrapersonal vulnerability factors and intrapersonal and interpersonal reinforcing functions. However, there were other parts of the ITM which were not investigated or evidenced, including distal risk factors, interpersonal vulnerability factors and the specific vulnerability factors of social learning and pain analgesia. It may be that the dynamic and complex nature of the ITM makes it challenging to test in its entirety.

Implications for future research

The small number of studies found within the current review highlights that this is an area in need of further research. The overlap in authors on the majority of identified studies, indicates there is a small group of researchers conducting pioneering research in the field of NSSI and ED. The high scores awarded to these studies in the quality appraisal demonstrates this is not viewed as a disadvantage.

A great deal of literature in this area has focused on correlates of NSSI within ED using cross-sectional studies, but these cannot be classified as risk factors as there is no indication of causality. More longitudinal studies are needed to improve the identification of risk factors. It is apparent improvements are needed for investigating risk factors and the two studies identified in the current review could have benefited from a longer follow-up period. The findings of Vansteelandt et al. (2013) could have also been strengthened by measuring acts of NSSI during the study duration to demonstrate whether affective variability temporally preceded NSSI, rather than retrospectively predicted it.

Future research would benefit from investigating factors, including identity formation and perfectionism, with a longitudinal design to understand whether they act as specific risk factors for engaging in NSSI in preference to other behaviours. Investigating the association of these factors widely in the general population of individuals who engage

in NSSI without an ED diagnosis could highlight whether they are more characteristic within an ED presentation only or NSSI in general.

The use of EMA to measure real-time emotional states by Muehlenkamp et al. (2009) would have helped to reduce confounding factors of recalling emotion experienced from retrospective acts of NSSI. Combining this method with self-reported motivation for NSSI (as measured in the other studies) and ED behaviours would provide more reliability in measuring function. It could provide an insight into how long- or short-lasting these reinforcing functions are and may help explain why some individuals repeatedly engage in NSSI. Assessing functions of ED behaviours and comparing this with functions of NSSI could be beneficial for understanding why they co-occur so frequently. A question to be considered could be, do ED and NSSI behaviours serve the same functions or do they provide separate types of reinforcement across different contexts and situations?

Measuring risk factors and functions with a combined sample of community and clinical participants, whilst controlling for ED severity and diagnosis, could be beneficial to ascertain whether clinical samples have a higher severity of ED.

Clinical Implications

The results of the current review would indicate that when working with individuals who have an eating disorder and/or engage in NSSI, a comprehensive risk assessment would be necessary. It would appear pertinent to assess difficulties in aspects of affect regulation and previous suicidal thoughts or behaviours.

With regards to intervention, the identified studies for both risk factors and function suggest that working therapeutically to reduce negative affect or increase positive affect may not be enough. It may be more beneficial for intervention to focus on the stabilisation of affect if the individual is prone to experiencing high levels of affective lability or variability in affect arousal.

The use of functional analysis has been recommended for investigating factors that reinforce NSSI and ED behaviours, across a range of situations (Andover, Holman, & Shashoua, 2014). This should then be used throughout intervention to test hypotheses and inform any changes needed, in the instance that new antecedents or reinforcers are uncovered.

Dialectical behavioural therapy is perceived to be an appropriate psychological intervention for individuals with NSSI and ED, as it incorporates modules on Emotion Regulation, Distress Tolerance, Interpersonal Effectiveness and Mindfulness (Walsh & Eaton, 2014). The results of this review would indicate that this could be an appropriate intervention. Due to the findings that perfectionism and self-criticism appear to be important factors in the co-occurrence of NSSI and ED, it may be that interventions such as compassion focused therapy may prove helpful to encourage the development of a more soothing inner dialogue and healthier alternative behaviours.

Limitations of the current review

A number of limitations warrant mention. Although the key word search of titles and abstracts was informed by previous literature in the field, it may have been subject to bias as the choice of key words was decided on by the primary author and this may have impacted on the number of studies included. The search was also conducted solely by the primary author.

The inclusion criteria were stringent with regards to including studies that confirmed ED diagnoses either clinically or by the research team in accordance with DSM/ICD classification systems. This resulted in the exclusion of studies that assessed ED by self-reported questionnaires, even if these measures met with DSM criteria. It is acknowledged that these restrictions may have excluded populations of individuals with sub-clinical or undiagnosed ED and reduced the number of studies identified. However, this review set out to provide a more rigorous review than conducted before and with the inclusion of both community and clinical samples, it was considered important to ensure that diagnosis had been reliably confirmed by clinicians or the research team across studies.

The search yielded a small number of studies, which makes it challenging to generalise to the wider population. None of the studies aimed to replicate the ITM and only a couple of studies explicitly made reference to the FFM (Nock & Prinstein, 2004). This review has imposed a theoretical framework onto their findings which they had not designed their studies to investigate.

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Service Improvement Project

Evaluating the integrated dual diagnosis dialectical behavioural therapy service in Bath and North East Somerset: An exploration of client and team member perspectives

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This journal publishes original research pertaining to the assessment, aetiology and treatment of people with a wide range of psychological difficulties, across a variety of settings.

Introduction

Overview of borderline personality disorder and dialectical behaviour therapy

Personality disorders are defined as complex and enduring maladaptive traits and patterns of behaviour that lead to significant personal distress and social dysfunction (American Psychiatric Association, 2000). The prevalence of personality disorder across North America and Western Europe has been reported as between 4-15% (Tyrer, Reed, & Crawford, 2015), with just under 1% of the UK general population having a diagnosis of borderline personality disorder (BPD; Coid, Yang, Tyrer, Roberts, & Ullrich, 2006). BPD is a type of personality disorder marked by instability in affect, behaviour, interpersonal relationships and sense of self (NIMH, 2016). Frequent parasuicidal behaviour, problematic substance misuse and emotional reactivity present a challenge to community mental health services attempting to provide effective treatment (Feigenbaum et al., 2012).

The National Institute for Clinical Excellence states that psychological interventions for the treatment of BPD should be provided for longer than three months and recommends the use of dialectical behaviour therapy (DBT) for females who engage in recurrent self-harm (NICE; 2009). DBT is a long-term, manualised cognitive behavioural treatment of up to two years, offering repetition of the yearly cycle of four modules: mindfulness, distress tolerance, emotion regulation and interpersonal effectiveness (Linehan, 2014). These are delivered through different components: weekly skills-based group training and individual therapeutic sessions, skills coaching through phone consultation and weekly consultation meetings for clinicians. With regards to its efficacy, a meta-analysis of five randomised controlled trials (RCT) found that DBT significantly reduced suicidal attempts and self-injurious behaviours, when compared to treatment as usual (TAU; Panos, Jackson, Hasan, & Panos, 2014).

The biosocial theory underpinning DBT proposes that individuals with BPD have a biological inability to regulate their emotions and behaviours, which is maintained and reinforced by an invalidating environment (Linehan, 2014). In the most severe cases this could involve abuse and neglect in childhood, but any environment that trivialises or dismisses the expression of emotion can become invalidating and teaches an individual that their understanding of experiences is wrong (McMain, Korman, & Dimeff, 2001). An understanding of this theory can assist the development of a non-pejorative,

compassionate and validating environment for clients (Swenson, Torrey, & Koerner, 2002).

Co-occurring BPD and substance misuse

Significant comorbidity has been found between BPD and substance misuse (Tomko, Trull, Wood, & Sher, 2014; Trull, Sher, Minks-Brown, Durbin, & Burr, 2000), with additional complexity in clinical presentation due to higher levels of impulsivity and increased drop-out rates from therapy (Kienast, Stoffers, Bermpohl, & Lieb, 2014). Increased complexity requires specialist treatment, yet literature on the efficacy of psychological interventions targeting both disorders is limited. A systematic review (Lee, Cameron, & Jenner, 2015) concluded that DBT demonstrated generally good outcomes in comparison to TAU and other treatments, including dynamic deconstructive therapy (DDP) and dual-focused schema therapy (DFST). Lee et al. (2015) suggest further research is required as results were based on a small number of DBT interventions with all-female participants and outcomes relating to reduced substance use and self-harming behaviour were varied.

Client and staff perspectives of DBT

Literature suggests that understanding the clients' perspective about the experience of therapy and factors that impact on therapeutic outcomes can both guide improvements to intervention and enhance theoretical understanding (Elliott, 2008). Studies focusing on the clients' perspective of DBT have found that engagement can lead to the development of a life worth living with positive changes in interpersonal relationships and control of emotions (Cunningham, Wolbert, & Lillie, 2004). It is suggested that engaging in DBT can be challenging, with high levels of emotion and difficulty in understanding the skills training material representing potential obstacles that require commitment and support to overcome (Barnicot, Couldrey, Sandhu, & Priebe, 2015). Considering the challenges that clients may face during the course of DBT, a recent study also explored the staff perspective and found they experienced the implementation of DBT to be intensive, with pressure to complete training and provide therapy within a tight schedule (Johnson & Thomson, 2016). Staff also commented on how DBT impacted on their personal and professional lives as they began to live by the model, rather than simply learning to teach it.

Rationale and aims of the project

The current study describes the evaluation of an innovative dual diagnosis DBT service in South West England that takes an integrated approach of one team addressing the needs of both BPD and substance misuse within one service setting. The rationale for the study was to expand upon literature by exploring both client and team member perspectives of a dual diagnosis DBT service, to gain a clearer understanding of factors that influence therapeutic outcomes and identify areas for service improvement. It aimed to:

- Evaluate client satisfaction with DBT, including their views on its individual components in helping to meet their needs.
- Explore team member perspectives about implementing DBT, their beliefs about what clients may value about the therapy being provided and their thoughts about current methods of measuring therapeutic outcomes and clinical effectiveness.
- Consider whether aspects of the service could be improved for the benefit of clients and the team, making recommendations based on the results of the evaluation.

Method

Study setting

The DBT service in Bath and North East Somerset (B&NES) was established by the Recovery and Therapies Team in 2007 and further developed in 2009 to run jointly with the B&NES Specialist Drugs and Alcohol Service (SDAS). The service comprises a range of professionals across the Therapies, Recovery and SDAS teams. The service has not previously conducted an evaluation.

Ethical Approval

Full ethical approval was gained from the University of Bath Psychology Department Ethics Committee (reference 16-132; Appendix B) and the Service Evaluation team of Avon and Wiltshire Mental Health Partnership AWP Trust (reference E2016.012 Lindsay; Appendix C).

Design

A cross-sectional design was employed, using mixed method analysis of questionnaire and interview data.

Measures

Questionnaires and interview schedules were developed for use in this study through discussion with all members of the research team.

Clients.

1. A 15-item questionnaire assessing satisfaction ratings for the service, the individual components of DBT and assessment phase (Appendix D).
2. A semi-structured interview assessing satisfaction and exploring aspects of therapy that are helpful/unhelpful (Appendix E).

Team members.

1. A 14-item questionnaire assessing ratings of quality of care delivered to clients, measures used to capture change and improvement and DBT training received (Appendix F).
2. A semi-structured interview assessing views on what clients might value about the service, thoughts on consultation, training and measuring treatment outcomes (Appendix G).

Participants

All current team members and clients were eligible to participate. The commissioners also wished to invite clients who had been discharged within the past six months, to capture the views of those with recent experience of completing the full course of therapy.

Clients.

3/4 current clients and 1/2 previous clients completed both the questionnaire and interview.

Team members.

5/8 current team members completed both the questionnaire and interview. Due to limited availability, one team member completed the questionnaire only.

Procedure

Clients were informed of the project and given an information sheet. After a two-week period for reflection on participation, written consent was obtained and clients contacted by telephone/email to arrange an interview time with the primary researcher. Team members were approached during their weekly consultation meeting and the same procedure was followed with regard to information sheets, obtaining consent and initial contact.

Analysis

Quantitative analysis.

Descriptive statistics (frequencies, percentages) were used to explore the data collected from the questionnaires.

Qualitative analysis.

7/9 interview transcripts were transcribed verbatim by the primary researcher. Two transcripts were transcribed verbatim by an independent researcher employed by the University of Bath. Thematic analysis was conducted according to the guidelines defined by Braun and Clarke (2006), shown in Table 2.1. They recommend that researchers decide on the approach and theoretical framework prior to analysis, hence, in this study themes were identified using an inductive approach, (e.g. driven by the data) and were analysed at a semantic level, reporting on the surface and explicit meaning of the data.

Table 2.1

Steps of thematic analysis as defined by Braun and Clarke (2006)

Step 1: Immersing yourself with the data through transcription and re-reading
Step 2: Generating initial codes by coding interesting parts of the data in a systematic way and gathering data extracts that match each code
Step 3: Searching for themes by collating codes and all data that is relevant to the theme
Step 4: Reviewing themes and generating a thematic map of the analysis
Step 5: Defining and naming themes with ongoing analysis In addition to the methodology defined by Braun and Clarke (2006), inter-rater reliability was conducted within this step. An independent researcher was given four transcripts to check for emerging themes. Interpretation of the data was discussed until consensus was reached on the main themes. One study has commented on the debate regarding whether qualitative data should be subject to verification by independent researchers as it is subjective by nature (Burnard, Gill, Stewart, Treasure, & Chadwick, 2008). However, they acknowledge that verification may increase rigour and reduce bias in analysis, which is the reason for its completion in this study.
Step 6: Producing the report with the selection of pertinent extracts from the data

Results

Quantitative analysis

Clients.

Clients had a mean age of 43.5 years (range= 40-47). One client was on their first cycle of DBT, two clients on their second and the fourth had recently been discharged. Demographics and clinical information are shown in Table 2.2.

Table 2.2
Demographic and clinical information of clients

	N (%)
Gender	
Male	2 (50)
Female	2 (50)
Modules completed	
Mindfulness	4 (100)
Emotion Regulation	3 (75)
Interpersonal Effectiveness	3 (75)
Distress Tolerance	3 (75)
Phone consultation used	
Yes	3 (75)
No	1 (25)

Figures 2.1, 2.2 and 2.3 show results from the questionnaire within three overarching domains respectively: Satisfaction with DBT components; helpfulness of individual DBT; other aspects of DBT.

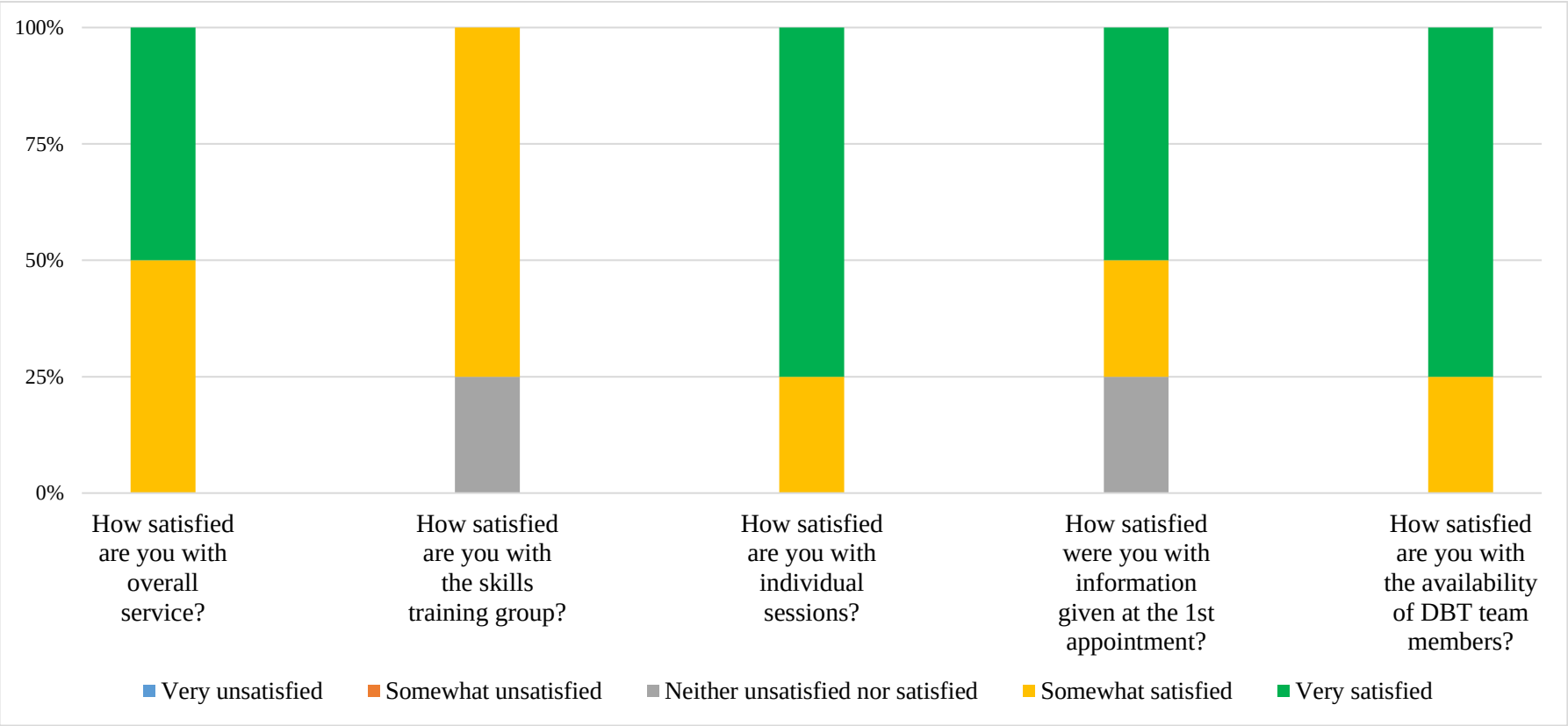

Figure 2.1 Satisfaction with the components of DBT

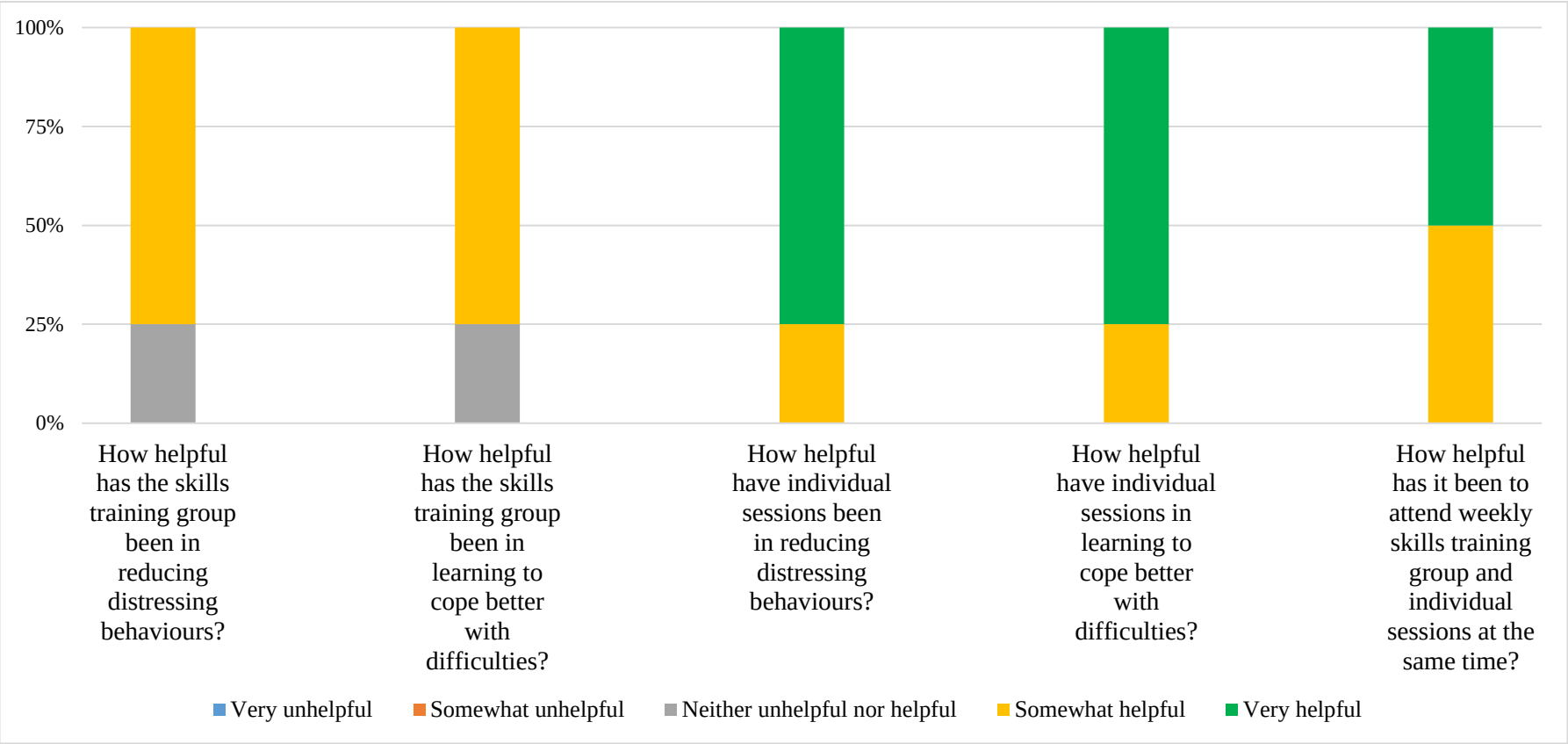

Figure 2.2 Helpfulness of the individual components of DBT in coping better and reducing distressing behaviours

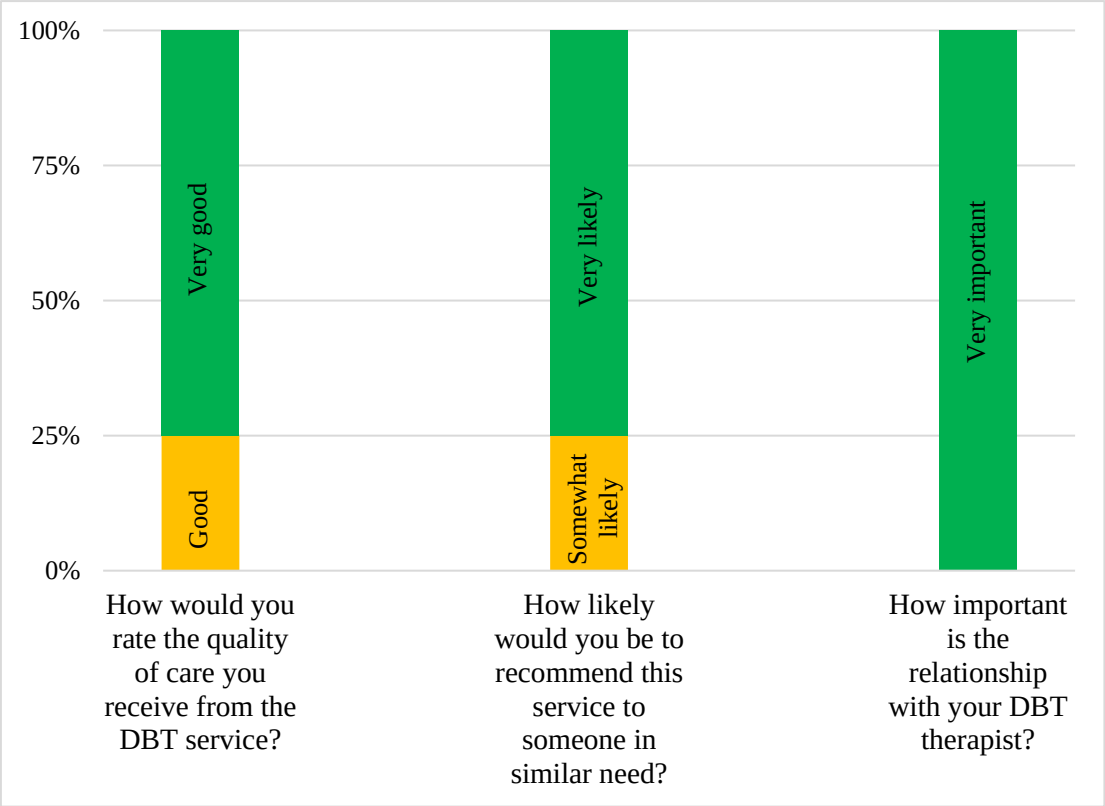

Figure 2.3 Ratings of other aspects of DBT

Team Members.

The mean length of employment within the DBT service was 3.26 years (range=7 months – 9 years). Demographics and information regarding provision of components are shown in Table 2.3.

Table 2.3
Demographic and provision of components by team members

	N (%)
Gender	
Male	1 (17)
Female	5 (83)
Job Role	
Clinical Psychologist	2 (33)
Specialist Recovery Practitioner	2 (33)
Social Worker	1 (17)
Senior Practitioner	1 (17)
Components of DBT involved with	
Skills training group	5 (83)
Individual therapy sessions	6 (100)
Phone Consultation	3 (50)
DBT assessments	6(100)
Consultation meetings	5 (83)

Figures 2.4, 2.5 and 2.6 show results from the questionnaire within three overarching domains respectively: Perceived quality and effectiveness of service delivered to clients; measuring change/improvement and use of materials; team only aspects of DBT.

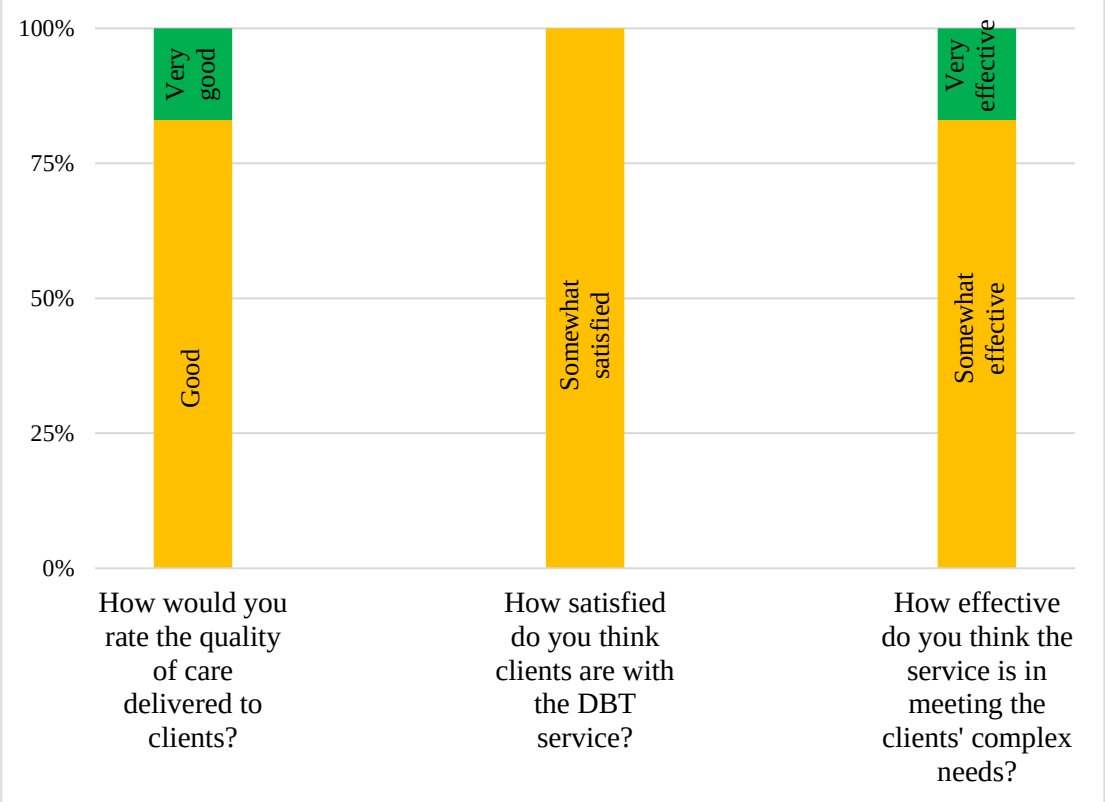

Figure 2.4 Ratings of perceived quality and effectiveness of service delivered to clients

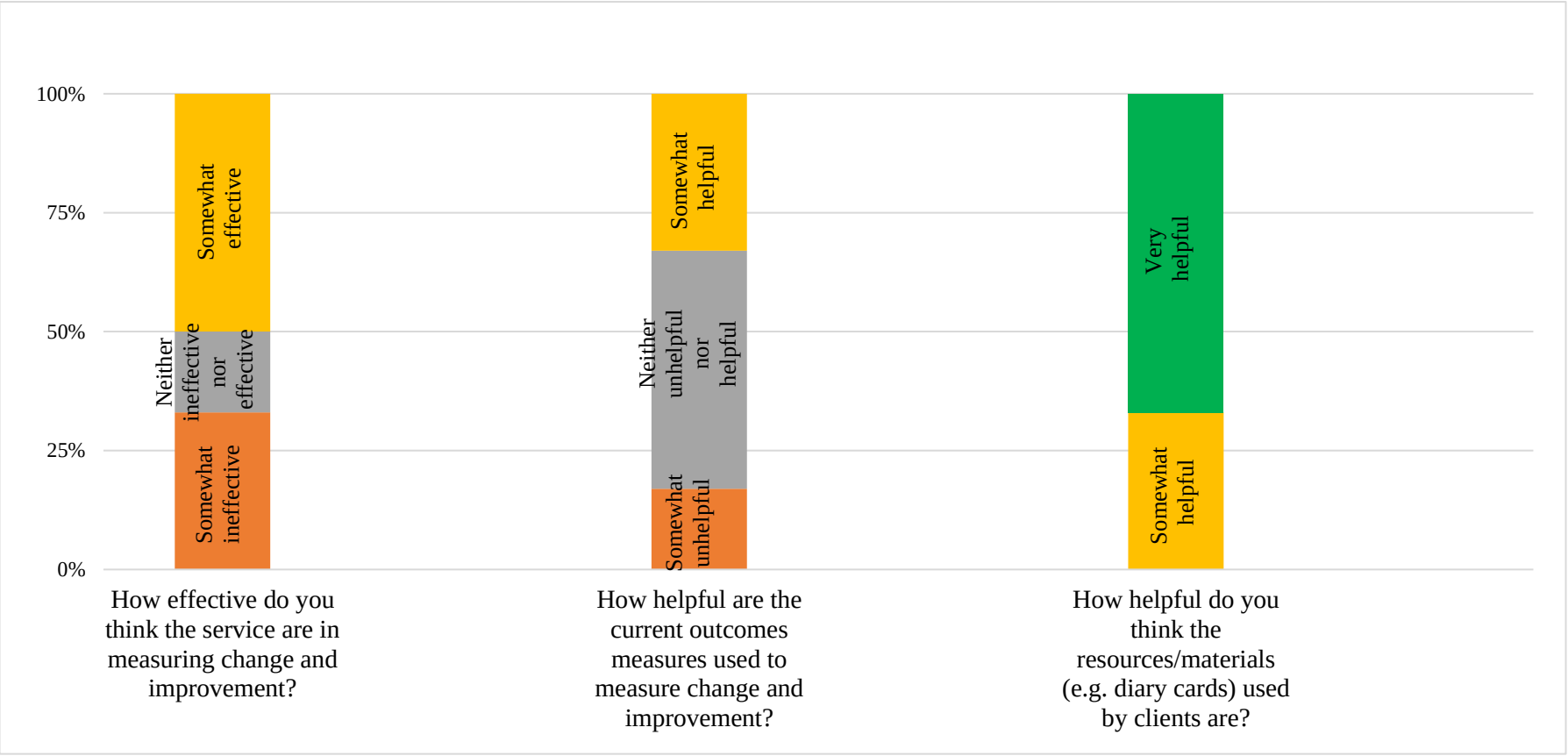

Figure 2.5 Measuring change/improvement and use of materials

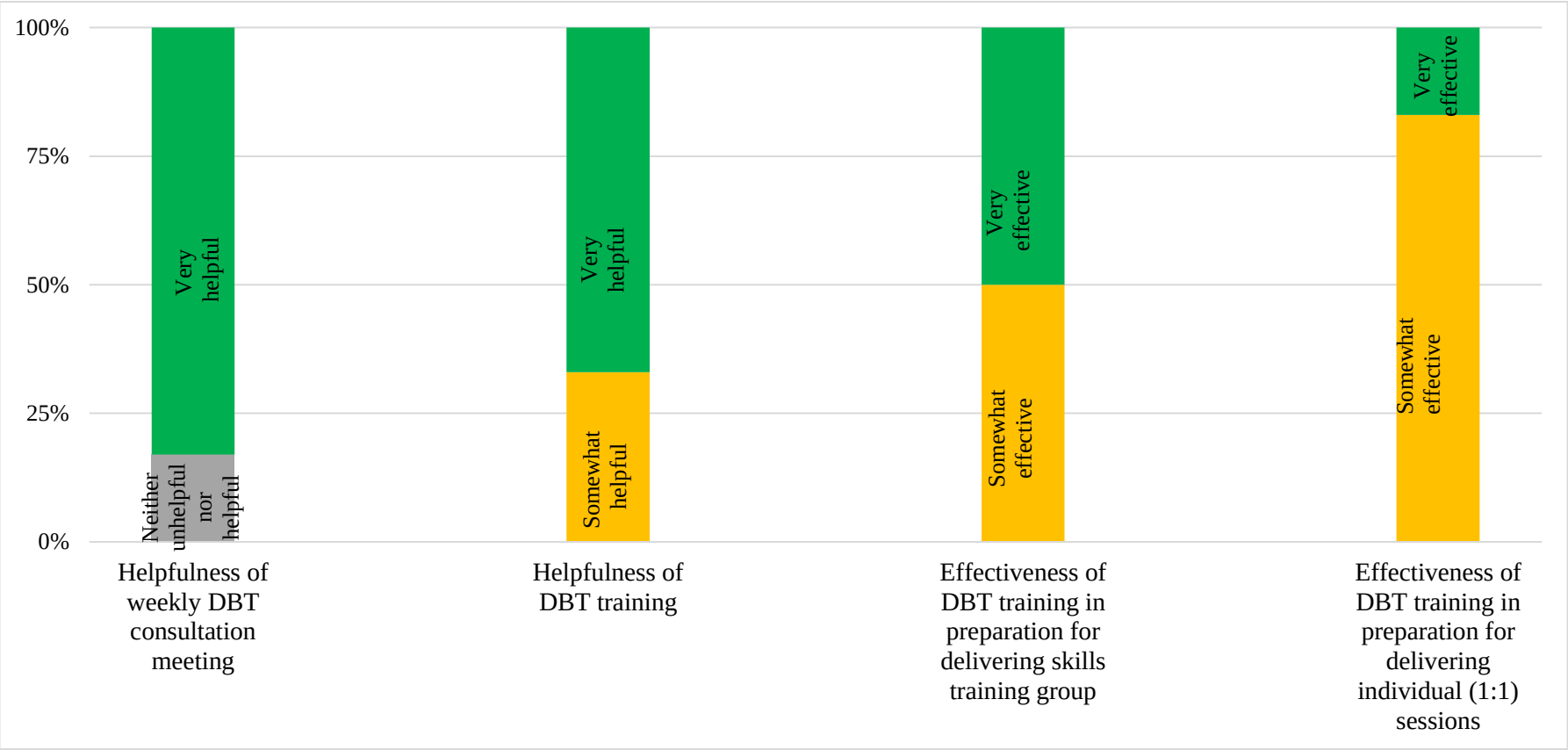

Figure 2.6 Ratings about team only aspects of DBT

Qualitative analysis

Clients.

Three main themes were derived and are shown in Table 2.4.

Table 2.4
Themes identified from client data

Main themes	Sub-themes
Building a life worth living	Mixed emotions beginning DBT
	Commitment and time
	Shifting perspectives and moving forward
	Resources as an aid
Challenging aspects of DBT	Painful emotions evoked
	Difficulties with self-criticism and self-confidence
	Individual differences in preference for and relevancy of skills
	Difficulties with the presentation of skills
The therapeutic environment	Therapeutic relationships
	Shared experiences in group
	Continuous support by phone
	Inflexibility in group sessions
	Inconsistent reinforcement of rules
	Preference for individual sessions
	Size of the group
	Venue

1. Building a life worth living

1.1 Mixed emotions beginning DBT

Many clients spoke about their belief that DBT could be a helpful therapy, when initially referred. However, one client described negative experiences prior to their DBT assessment, including a long waiting time and miscommunication.

"I think people- mental health services think that people with personality disorders are difficult and awkward and can't be treated" (1)

A couple of clients reported feeling "*worried"* they may not have been suitable for DBT and there may have been no alternative offered.

1.2 Commitment and time

All clients described starting DBT with the desire to achieve life-changing goals, including becoming "*emotionally stable"* and learning "*to tolerate immediate distress."* Some spoke about wanting to learn "*normal"* coping mechanisms. One participant spoke about the DBT team managing their expectations during assessment.

"It was helpful in so far as allowing me to understand what DBT could do and couldn't….so my expectations were managed more appropriately" (4)

One client had the realisation that there was "*no magic cure*," and that it may take time to overcome long-term difficulties. Clients described their decision to "*give it a go*" and commit to the long course of therapy.

1.3 Shifting perspectives and moving forward

For some clients, the content of skills training had helped to move forward with alternative coping strategies and the reduction of target behaviours.

"DBT is more now about what it should be about, which is building a life worth living" (3)

Others spoke about how DBT had shifted their perspective on situations.

"Say there's a situation that you can't change, rather than trying to change it you think 'right that's the way it is'" (2)

1.4 Resources as an aid

For some, the resources used in DBT were helpful for learning and practising skills between sessions.

"Diary cards are really good and I think it's probably something I would use even after because it just keeps me aware of my moods and things I've been doing" (2)

Some clients spoke about their desire to have additional resources available, including books and mindfulness exercises to develop their understanding and practice of skills.

2. Challenging aspects of DBT

2.1 Painful emotions evoked

Clients reported that engaging in individual and group sessions could be painful and upsetting.

"Changing how you view a certain situation, as painful as that might be, it's still helpful to do" (4)

One client described apprehension about sharing examples within the group, for fear of upsetting other clients.

"They'll say 'can you give us examples', and you know what?, you can't because it could impact on somebody else" (3)

2.2 Difficulties with self-criticism and self-confidence

Some clients reported treatment goals of developing self-worth and confidence and described how modules could trigger negative feelings about themselves.

"Each time we start with something new, a new session, I do have an emotional reaction straight away that I'm being told this is all my fault" (1)

Clients spoke about how self-worth has acted as a barrier to engagement with aspects of therapy.

"Learning about being nice to yourself, kind to yourself, that was an alien concept to me" (4)

2.3 Individual differences in preference for and relevancy of skills

Clients described not all skills taught as helpful or relevant to them personally.

"I don't think I use any more than twenty percent of what I've been taught but that twenty percent is important" (3)

Clients were respectful of one another and acknowledged how others may benefit from different skills.

"Some of them I think, 'actually this isn't really for me' but I accept that probably somebody else, they could be having their big wow moment" (2)

2.4 Difficulties with the presentation of skills

All clients described negative aspects about the presentation of skills, including a *"large volume of information,"* culturally different examples and a gender bias in examples that favour women.

"It's Americanised as well…and wordy" (2)

"The examples they are giving are of female domestic abuse and you're thinking 'well where are the male victims then?'" (3)

Homework was described as challenging, with a suggestion that it may not be taken seriously by both clients and DBT team members, resulting in it not being completed. Some clients expressed a preference for more time to be given to understanding and practising homework.

"I think probably right from the word go DBT facilitators have kind of joked about homework and how people find it really difficult to do" (1)

3. Therapeutic environment

3.1 Therapeutic relationships

Clients spoke about the value of developing validating, respectful therapeutic relationships with their individual therapist. Some spoke about the importance of their therapist treating them as an individual, sharing humour and challenging them when needed.

"I felt I could trust her with my thoughts and feelings - things that I'd never shared with anybody else and I never felt judged and having someone like that in my life was just yeah incredible" (4)

Some clients described how group facilitators can help to create a *"safe"* and *"non-judgemental"* space within skills training sessions.

3.2 Shared experiences in group

Some clients described being in group therapy perhaps not suiting them initially.

"I've never done groups, I quite like my own company, like my own space" (2)

However, all clients reported the importance of the peer aspect of the group in their experience of DBT.

"The helpful aspect of that was that it, you were in a room with like-minded people who suffered maybe in different ways but we all had a common reason for being there" (4)

However, two clients commented on the rolling nature of the group and how "*different people can change the dynamics of the group,"* which can bring *"anxiety."*

3.3 Continuous support by phone

For some clients, the provision and option of phone support between sessions was a valuable addition, with those who had used it describing how it brought comfort.

"Just to hear their voice and feed it back and go 'oh yeah ok that's fine', cos it breaks your state, it breaks your emotional turmoil" (3)

Some clients had experienced difficulties with this, including messages not being passed onto their individual therapist and not being able to call outside of working hours. One client didn't like the thought of speaking to someone that they didn't know and thought that *"it may make it worse."*

3.4 Inflexibility in group sessions

Some clients found the set agenda of group sessions to be unhelpful, particularly when experiencing crisis or finding certain skills hard to learn.

"There's not a lot of flexibility; it would be difficult to kind of sidetrack off and say 'I haven't had a great week' or 'I'm struggling at the moment'" (1)

One client described how this affected the way that they experienced group sessions.

"I need to talk about that now, not in three days' time, so I would go away very often completely disoriented and deflated and distressed" (3)

3.5 Inconsistent reinforcement of rules

Clients expressed that they did not agree with some rules of DBT and felt there were inconsistencies in their reinforcement across teams.

"I think [SDAS] were maybe just a little bit more forgiving of people and their situations if they understood why somebody had missed appointments" (4)

Another client reported calling ahead of their weekly session to cancel due to sickness but still receiving an absence letter.

"You still get a letter saying that if you don't turn up next week you're out and I find that a little bit childish and a little bit dictatorial really" (3)

3.6 Preference for individual sessions

All clients spoke about how important their individual therapy sessions were and for some, this was the most critical component of DBT.

"I don't think I would be sat here to be honest if it weren't for the one-to-ones" (3)

Clients spoke about valuing the "*flexibility"* and individualised nature of individual sessions.

"If there are things you are struggling with you can work on those a bit further in those sessions" (4)

3.7 Size of the group

Two clients reported that whilst a smaller group encourages participation, it may benefit from being bigger.

"I think it probably would help to be slightly bigger……I'm forced at the moment to take part. Not forced but if they say 'think of an example' I've got to think of an example, or I feel I've got to." (1)

One client expressed disbelief at the small number in the group within the region.

"I can't believe there's only four people in the Bath area that could benefit from DBT!" (1)

3.8 Venue

Clients reported some issues with the current venue for group sessions, including difficulties with parking and disruptive noise.

"When you're trying to meditate and things like that it was particularly difficult, so a quiet or a more suitable environment would be good" (4)

Team members.

Two superordinate themes emerged, as shown in Table 2.5.

Table 2.5
Themes identified from team member data

Superordinate themes	Main themes	Sub-themes
Not a dedicated DBT service	Lack of protected time	DBT as 'extra'
		Consequences of lack of capacity
		Time needed as a team
	Growth	Defining where the service sits within a treatment pathway
		Expansion of the service
		Improving retention
	Evaluating outcomes	Inconsistency and uncertainty about measurement
		Qualitative feedback
	Learning the material	Overwhelming amount for the clients and the team
		Continuous practising of skills
Provision of DBT	Consultation is critical	Containing and safe space for the team
		Modelling the model
	The client experience	Importance of individual sessions
		Peer aspect of the group
		Intensity and a high level of input provides containment

4. Not a dedicated DBT service

4.1 Lack of protected time

4.1.1 DBT as 'extra'

Team members reported that the provision of DBT is additional to their current caseloads. They expressed a desire to have *"dedicated"* time rather than having to "*carve"* out time in their already busy working weeks.

4.1.2 Consequences of lack of capacity

Team members discussed how limited capacity disrupts the provision of components, including individual sessions. One member described that the service was "*not so great at"* phone support. The separate geographic locations of the teams were raised as possibly affecting attendance at consultation and clients knowing which team number to phone for support.

"When I'm not running the group, it can feel a real pressure, to come, to come to NHS House for two hours for consultation" (2)

4.1.3 Time needed as a team

Whilst consultation is a time to discuss business aspects and the overall running of the service, team members felt as though this was not enough and expressed a desire to arrange additional time as a team.

"We could try for the service itself planning an Away day, an afternoon of just being able to plan ahead and be more thoughtful" (5)

4.2 Growth

4.2.1 Defining where the service sits within a treatment pathway

One team member reported that defined treatment pathways for DBT were needed to help decide when it is the most appropriate treatment in relation to other therapies.

"I think it's important the service is considered as part of a broader pathway for service users with these difficulties" (1)

Another team member spoke about uncertainty regarding whether DBT should only be a *"stabilisation"* phase, with additional treatment offered afterwards.

4.2.2 Expansion of the service

Team members proposed ideas for how the service could be expanded to reach a greater number of people within the region, including becoming a dedicated service to be able to steadily accept referrals and developing additional skills training groups.

"We do have that group of people that significantly lack skills and could benefit from distress tolerance, emotional regulation, mindfulness and interpersonal effectiveness but they're not self-harming or they're not engaging in life threatening behaviours" (5)

4.2.3 Improving retention

For some team members, they believe that spending more time providing additional "*pre-DBT*" sessions may prevent people "*from dropping out"* by allowing more time to understand what DBT will involve.

4.3 Evaluating outcomes

4.3.1 Inconsistency and uncertainty about measurement

Some team members were "*unsure"* of which measures were used and how often they were administered, whilst others acknowledged that there was inconsistency in this.

"They haven't been given regularly at the end when people have finished the service" (1)

One member described that the team *"haven't got a proper process"* for storing measures and that it was unclear who had responsibility for scoring and interpreting them. Team members reported that diary cards can be useful for monitoring target behaviours. One member questioned whether the completion of modules and learning DBT terminology may "*train them* [clients] *to answer the questionnaires"*, affecting scores captured at the beginning and end of therapy.

4.3.2 Qualitative feedback

Many team members acknowledged that they did not know how satisfied clients were with the service but that they would be *"interested"* to hear feedback.

5. Provision of DBT

5.1 Learning the material

5.1.1 Overwhelming amount for clients and the team

Some members described the skills training material as overwhelming for both clients and therapists.

"We're trying to teach some really important skills and encouraging important insight into behaviours and I think that gets lost because of the volume of information that we have to impart" (2)

Some team members described feeling "*unprepared"* to deliver individual and group sessions after the short period of training they received.

5.1.2 Continuous practicing of skills

All team members reported that DBT training was *"helpful"* and encouraged in-vivo practice of skills that mirrored the delivery of skills training to clients.

"We were being told to do repairs and forced to do things in front of other people, which was slightly uncomfortable, which I think was no bad thing" (3)

Many team members felt that continued practise of skills and *"learning on the job"* helped to deepen their knowledge of DBT.

5.2 Consultation is critical

5.2.1 Containing and safe space for the team

All team members discussed the importance and value of attending consultation, describing the "*containment"* it offered, with reflection on difficulties and anxieties that may arise from working with high-risk clients.

"It's really valuable and it's really worth ring fencing….it helps in terms of clinician burnout" (4)

5.2.2 Modelling the model

Some team members reported that consultation is helpful when it is structured and adheres to the DBT model, including the use of mindfulness and assigning roles of chair and minute taker.

"[bringing a supervision question] *reminds us what the DBT model is and it's more like DBT supervision as opposed to more just general feedback" (1)*

5.3 The client experience

5.3.1 Importance of individual sessions

Team members reported that individual sessions are "*essential"*, as they allow personalisation and tailoring of skills to benefit each client. They described it as a private space to discuss target behaviours and personal circumstances away from the group.

5.3.2 Peer aspect of the group

It was acknowledged that clients derive benefits from being in a group with peers.

"Being in a group with other people is helpful for other service users, each service user, because they can see they're not on their own, that there are similar struggles, different struggles that people are experiencing." (2)

5.3.3 Intensity and a high level of input provides containment

Team members perceived that clients value the high level of input provided with DBT and described how this is a *"significant increase in the delivery of care"* that other services may offer. There was acknowledgement that the structure and validating therapeutic relationships may be important for this client group.

"DBT is the container in which people are allowed to have an intensive therapeutic relationship with someone, and someone who's not kind of blown away by their kind of *chaos and kind of difficulties they are having in their life, which I think for a lot of people they have had" (3)*

Discussion

This study was designed to explore client and team member perspectives of DBT. The first aim was to evaluate client satisfaction with components of DBT in helping to meet their needs. Results from the clients' quantitative analysis demonstrated that, generally, they have high levels of satisfaction with the service, aspects of DBT and the therapists who deliver it. Patterns indicated clients' preference for individual sessions, which they rated as being more helpful in learning to cope better with difficulties and in reducing behaviours that may be distressing. Qualitative analysis reflected this pattern of results, with clients valuing the personalisation of individual sessions and the development of validating therapeutic relationships.

The second aim was to explore team member perspectives about implementing DBT and their thoughts about what clients may value about the service they receive. The quantitative analysis suggested they are a team that perceive themselves to be providing a good level of service which their clients value but they do not think they are capturing change and improvement in the most effective way. Qualitative analysis demonstrated that the team experience a pressured working environment, with a lack of dedicated time and resources available to deliver a level of service they aim for.

Similarities between the client and team member data

There were several similarities between the data of clients and team members. Clients' ratings of high levels of overall satisfaction with the service was comparable to the team's perceived client satisfaction. Clients ('Preference for individual sessions') and team members ('Importance of individual sessions') spoke about the value of individual sessions in providing a flexible space for clients. Team members acknowledged the benefit that clients reported gaining from being in a group with others who experience similar difficulties (team: 'Peer aspect of group'; client: 'Shared experiences in group').

The team member sub-theme 'Intensity and a high level of input provides containment' reflected on how the structure of DBT empowered clients and provided a *"sense of agency."* This is similar to the client sub-theme 'Therapeutic Relationships,' which captured how they perceived positive therapist qualities, including empathy and a non-judgemental stance, as important factors in developing a trusting therapeutic alliance. Research has found reduced levels of non-suicidal self-injury amongst clients in DBT who perceive higher levels of understanding and involvement from their therapist (Bedics, Atkins, Harned, & Linehan, 2015). Although team members infrequently mentioned the therapeutic alliance, there was an inherent sense of compassion and sincerity towards clients that underpinned their data and this may be what helps clients to feel validated and valued. It is unknown whether team members were being modest about the personal qualities that they may bring to DBT, or perhaps interview questions were not specific enough to capture their views on this. In any case, when working with a client group that may experience significant disturbance in interpersonal relationships (Bender, 2005), it appears a strength of the service that strong therapeutic alliances are formed.

The experience of team members in learning the DBT material (main theme 'Learning the Material) appeared to mirror that of clients (sub-theme 'Difficulties in the presentation of skills) as they both acknowledged the pressure and challenge of attempting to learn the information. Comparable to the clients finding it difficult to use skills, team members also demonstrated they can find it challenging to consistently practise skills and stick to the model, particularly within consultation. The negative aspects of the presentation of skills reported by clients was similar to a previous qualitative study with individuals who had either completed or dropped out of DBT (Barnicot et al., 2015). The authors of this study suggested that DBT therapists could consider these barriers to skills training as 'therapy interfering behaviours' and monitor these by adapting diary cards, to help validate and respond to client difficulties. One male client spoke about how the gender bias they perceive in DBT material can negatively affect their engagement with particular skills. Females do appear to be given a diagnosis of BPD more frequently than males (Bjorklund, 2006) and DBT was developed specifically for females with BPD, with the literature into its efficacy focusing on female samples. In contrast, literature into the use of DBT with male populations tends to focus within forensic settings, without acknowledging that males may not always be perpetrators of violence. This perhaps suggests the need for more research that considers adaptations of the DBT material, making it more generalisable to males.

Working as a team

In relation to the team member superordinate theme of 'Not a dedicated DBT service,' it is recognised that mental health services in NHS England are significantly underfunded and that this can impact on the wellbeing of staff (Mental Health Taskforce, 2016). The lack of protected time for DBT reported by the service may be one of the reasons that they view consultation to be a vital aspect of their role as it provides much needed support from colleagues. One team member recognised the power of using consultation to protect against clinician burnout when working with a high-risk client group. Working across three teams appears to bring an additional layer of complexity and highlights the practical difficulties of implementing integrated care, ensuring that the team is cohesive and well supported.

Recommendations

Based on the findings, recommendations were made which could lead to improvements in the service to benefit both clients and team members. These are shown in Table 2.6.

Table 2.6

Recommendation for service improvement

Client-focused recommendations
1. Improving client experience • Based on client feedback regarding negative experiences of miscommunication and the provision of limited information about DBT prior to a referral being made, it may be beneficial to provide **information sessions/leaflets for GPs, primary care assessment teams, care coordinators that explain the overarching aims of DBT**. • **Reiterating rationale for the structure and rules of DBT** (e.g. not discussing target behaviours in group sessions) may help clients to understand why rules are in place. • Based on client feedback, it would be helpful to have **improved consistency across the three teams, regarding letters being sent out after non-attendance of group and individual sessions**.
2. Presentation of skills in group sessions • To help reduce painful and upsetting emotions that may have been evoked and to aid understanding of skills covered in session, **checking understanding and allowing discussion before finishing the session** may be helpful. • **Reiterating the importance of homework and allowing time in session to discuss it and possibly complete a dummy run**, may improve compliance of homework and encourage therapeutic change. • **Adjust skills-training examples from the DBT manual to become more culturally relevant** for all clients. • The use of **DBT YouTube videos, phone applications and websites** may encourage further learning and practice at home and increase client agency in the use of skills.
3. Phone consultation • **Advising clients of availability for phone support during office hours 9-5pm (e.g. days of work)** may prevent disappointment for clients if they know that team members are not working. • **Ensure clients are aware of contact numbers for urgent situations** (e.g. intensive team/A&E) • It may be helpful to **compile a list of team member office phone numbers** for clients to know which number is most appropriate. • **Ensuring that administrative staff know who DBT team members are and how they can be contacted**, may prevent messages not being passed on and clients' phone calls not being returned
Team-focused recommendations

4. Measuring outcome and improvement
• To improve the practical aspects of data record-keeping:
  o **Designate storage space for paper copies of measures**
  o **Set up a shared spreadsheet and file for electronic storage of data from outcome measures.**
  o **Keep master copies of measures in one file with guidance for scoring and interpretation**
• To improve validity of questionnaires:
  o **Discuss the client's understanding of measures during assessment**
• To improve consistency in measurement:

- **Decide as a team about the best time to administer outcome measures** (e.g. yearly review) and **what data would be helpful to capture** (e.g. diary card target behaviours, A&E admittance, verbal feedback)
- **Ensure measures are completed upon discharge from the service**

5. Consultation meetings

- Based on team member feedback it could be helpful to improve the structure of consultation meetings and adhere to the DBT model on a more regular basis:
  - **Assign a chair and minute taker** (a rotation list could help to make these fair)
  - **Setting the agenda at the start**; prioritising topics and allocating time
  - **Bring a supervision question** regarding a case or the discussion of a particular skill - this could help to provide a refresher of information about skills
  - **Allow short amount of time for informal discussion, colleague support** if needed
  - **Do something positive or motivating at start if staff lethargic, stressed** – based on feedback, mindfulness may help with this

6. Time together as a team

- As team members suggested, **organising a team Away Day** could provide valuable protected time to discuss the implementation of ideas that the team already have e.g. peer involvement, additional pre-DBT sessions
- This could involve discussion about how to liaise with commissioners regarding becoming a dedicated service and considering treatment pathways for DBT

Feedback and dissemination

Quantitative data, main themes from the thematic analysis and recommendations were presented to the DBT clients and team. Team members described the results as "*positive"* and were pleased to hear that clients reported good overall levels of satisfaction with the service. The clients reported that the results reflected what they had said. The team welcomed recommendations and appeared keen to implement those related to consultation and the presentation of skills. An Away day has been arranged for June 2017, which will provide the team with time to consider other recommendations and the primary researcher has been invited to attend.

Limitations

This evaluation utilised a cross-sectional design with a small sample of participants, which limits its ability to generalise the results. The small sample makes it difficult to ascertain whether saturation was achieved in the qualitative data, however, there was a

high response rate from participants who were approached. With team members working across difference services and DBT not being their primary focus of work, this may have contributed to the lack of saturation in their data, as they may have various working practices and approaches.

The small sample of clients was not fully representative of all individuals who may have been eligible to participate as there were three additional clients who had started DBT within the past year and dropped out of therapy in the early phases of treatment. It was not possible to contact these individuals regarding participation but this may have introduced bias into the findings. Including their perspectives could have provided valuable insight into factors that contributed to their discontinuation with DBT and may have had an impact on the recommendations made for service improvement. It is possible that clients who commit to two years of treatment will have a level of satisfaction that maintains their engagement.

In conclusion, this study aimed to evaluate an integrated dual diagnosis DBT service by exploring client and team member perspectives. Results showed that clients had a high level of satisfaction with the service, citing the therapeutic relationship and individual sessions as important, with difficulties experienced in the presentation of skills and the inflexibility of group sessions. Team members described delivering a service that they perceived to be of good quality that they felt clients were satisfied with. They spoke about finding it difficult to provide some components due to not being a dedicated DBT service and described challenges in measuring outcomes.

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Main Research Project

Exploring the role of mental defeat, fear of cancer recurrence and health-related beliefs in distress and quality of life amongst cancer survivors experiencing cancer pain and cancer-related fatigue

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Target Journal: Psycho-oncology
This journal publishes original research pertaining to the psychological responses of people with cancer at all stages of the disease.

Introduction

With a general population that is living longer than ever before, it is currently predicted that by the year 2020 one in two people will receive a diagnosis of cancer in their lifetime. Advances in detection and treatment has increased survival rates with 50% of people diagnosed in England and Wales surviving for at least ten years (Cancer Research UK). The term 'cancer survivor' has been defined as broadly referring to any individual from the time of diagnosis, throughout the rest of their life (Denlinger et al., 2014): this definition will be used here. Currently, there are approximately two million cancer survivors living in the UK, of whom up to a quarter are estimated as experiencing poor physical and psychological health, as a consequence of living with the illness (Macmillan Cancer Support, 2013; Maddams, Utley, & Møller, 2012). The present study intended to improve understanding of poor psychological health and quality of life, occurring as a consequence of cancer survivorship.

Although many people show satisfactory psychosocial adjustment and resilience after cancer treatment (Costanzo, Ryff, & Singer, 2009; Stein, Syrjala, & Andrykowski, 2008), others thus struggle to adjust to life after treatment and experience anxiety and uncertainty about their future (Brennan, 2004). Physical and psychological problems can persist for months to decades (Stanton, Rowland, & Ganz, 2015) and in many ways cancer survivorship for some is experienced as a chronic illness, often characterized by a range of debilitating experiences such as mood changes, fatigue and pain (White, 2001).

Cancer-related fatigue (CRF) and moderate to severe cancer pain are two of the most prevalent physical consequences of living with cancer occurring in up to 75% and 33% of survivors respectively (Macmillan Cancer Support, 2013). CRF is one of the most common symptoms experienced by cancer survivors, defined as tiredness and exhaustion which appears out of proportion to levels of exertion and is not relieved by rest (Berger, Gerber, & Mayer, 2012). It may be a consequence of either the cancer itself or treatment (Berger et al., 2012) and may be experienced before, during and after treatment, leading to impairment in daily activities and lower quality of life (Hofman, Ryan, Figueroa-Moseley, Jean-Pierre, & Morrow, 2007). A systematic review found that CRF is consistently associated with depression and to a lesser extent anxiety, although the direction of causality of these relationships is difficult to measure due to multiple interacting factors (Brown & Kroenke, 2009).

Cancer pain is commonly experienced as a consequence of the condition and is experienced by individuals at varying stages of their cancer trajectory, including during active treatment and after completion of curative treatment (van den Beuken-van Everdingen, Hochstenbach, Joosten, Tjan-Heijnen, & Janssen, 2016). It has been found to be associated with poorer physical and social functioning (Green, Hart-Johnson, & Loeffler, 2011), anxiety, depression and catastrophising (Belfer et al., 2013). Findings suggest that cancer pain may have a direct effect on CRF (Beck, Dudley, & Barsevick, 2005) and when poorly managed it can contribute to daytime fatigue (Franklin & Packel, 2006). It has also been found to share some of the features of chronic fatigue syndrome (CFS; Bourke, Johnson, Sharpe, Chalder, & White, 2014; Surawy, Hackmann, Hawton, & Sharpe, 1995) in terms of the experience of both physical and psychological symptoms.

The relationship between physical and psychological symptoms in the context of cancer survivorship will be influenced by the meanings attached (White, 2001). Leventhal's illness cognitions and Self-Regulation Model of health suggests individuals use cognitive and emotional processes to interpret health threats and consider their identity (e.g. label assigned to the symptom), perceived cause, expected duration and possible consequences (Leventhal, Leventhal, & Contrada, 1998). These illness representations subsequently affect one's understanding and coping strategies; threat beliefs in particular may be best considered within the context of cognitive approaches to anxiety, pain and health fears (Warwick & Salkovskis, 1990).

Cognitive theories of pain have suggested negative cognitions, such as catastrophising and pain-related fear, can perpetuate the illness, developing acute pain into a chronic condition (Lethem, Slade, Troup, & Bentley, 1983; Vlaeyen, Kole-Snijders, Boeren, & van Eek, 1995). Attentional focus and hypervigilance to bodily sensations may lead to catastrophic interpretations that they are a sign of deterioration, increasing fear of injury and avoidance of activity; maintaining the vicious cycle of fear-avoidance and exacerbating disability, pain and distress (Schütze, Rees, Preece, & Schütze, 2010). Similarly, the experience of chronic fatigue is affected by an individual's interpretation of the cause and meaning of bodily sensations and symptoms experienced (Afari & Buchwald, 2003). As with pain, individuals with fatigue may interpret the presence of symptoms as an indication that their condition is worsening, resulting in an avoidance of activity (Surawy et al., 1995). In both conditions, increasing chronicity is accompanied by preoccupation with symptoms, a perceived lack of control, demoralisation and a sense

of hopelessness (Osborn & Smith, 1998; Surawy et al., 1995). Thus, CRF and cancer pain are crucial in the experience of distress and poor quality of life; however, psychological factors can be regarded as influencing this. Potential factors will be considered next.

Experiencing ongoing physical symptoms as a cancer survivor, such as cancer pain and CRF, is associated with elevated 'fear of cancer recurrence' (FCR) and increased psychological distress (Crist & Grunfeld, 2013). Many cancer survivors report experiencing FCR which is defined as fear, worry, or concern that cancer may return or progress in the same or a different part of the body (Lebel et al., 2016). A degree of FCR is understandable and supports ongoing helpful behaviours, such as engagement with medical follow-ups and healthy lifestyles (Simonelli, Siegel, & Duffy, 2016). However, persistent and prominent levels of FCR can lead to greater psychological distress and lower quality of life (Simard et al., 2013).

To develop a shared understanding of FCR, a formulation has been proposed which outlines how internal (e.g. physical symptoms) and external (e.g. medical appointments) stimuli may trigger cognitions, such as one's perception of the likelihood of experiencing recurrence, previous memories of cancer and knowledge about survival rates (Lee-jones, Humphris, Dixon, & Bebbington Hatcher, 1997). These thoughts give rise to anxious emotions and individuals may engage in health-related checking behaviours (e.g. reassurance-seeking and body checking) in an attempt to relieve anxiety.

There are similarities between FCR and health anxiety, including high levels of preoccupation with health, maladaptive coping behaviours and the misinterpretation of symptoms as more serious than they really are. However, health anxiety is rarely mentioned in the context of cancer survivors, although it has been considered that it may become a problem in cancer remission, with increased reassurance-seeking behaviours (Stark et al., 2004).

Some survivors experiencing physical symptoms, such as pain and fatigue which they relate to cancer, may experience particularly intense fears of recurrence, potentially attributing these symptoms to the return of cancer. This corresponds to the construct of catastrophising, in which a person thinks the worst based on their interpretation of symptoms. Physical symptom catastrophising is characteristic of health anxiety. The construct of 'mental defeat' is a subtly different type of catastrophising, reflecting highly

negative beliefs about the self and, in particular a "loss of agency". Mental defeat is defined as a perceived loss of autonomy and identity as a human being, to the extent that individuals abandon attempts to retain this (Ehlers et al., 1998). Mental defeat has been found to be an important psychological phenomenon within chronic pain (Tang, Beckwith, & Ashworth, 2015; Tang, Goodchild, Hester, & Salkovskis, 2010; Tang, Salkovskis, & Hanna, 2007), post-traumatic stress disorder (PTSD; Ehlers et al., 1998; Ehlers, Maercker, & Boos, 2000) and depression (Gilbert & Allan, 1998).

In chronic pain, individuals with mental defeat feel overcome by pain and hold negative beliefs about themselves in relation to it, catastrophising about the way in which pain is controlling and destroying their life, autonomy and identity (Tang et al., 2007). The presence of mental defeat has been found to be a strong predictor of psychological distress and is associated with higher levels of functional and psychosocial disability, sleep interference (Tang et al., 2010) and more recently with suicidal ideation (Tang et al., 2015). The literature on mental defeat in depression and PTSD (Ehlers et al., 1998; Gilbert, 2006) has also found it to be a cognitive predictor of symptom severity and poor treatment outcomes. The persistence of both pain and fatigue in cancer survivors would be likely to engender particularly higher levels of mental defeat, related to the perceived impact on the cancer survivor's life and future. Figure 3.1 indicates how quality of life and psychological distress will be impacted by these catastrophic interpretations in relation to the experience of cancer pain and/or CRF.

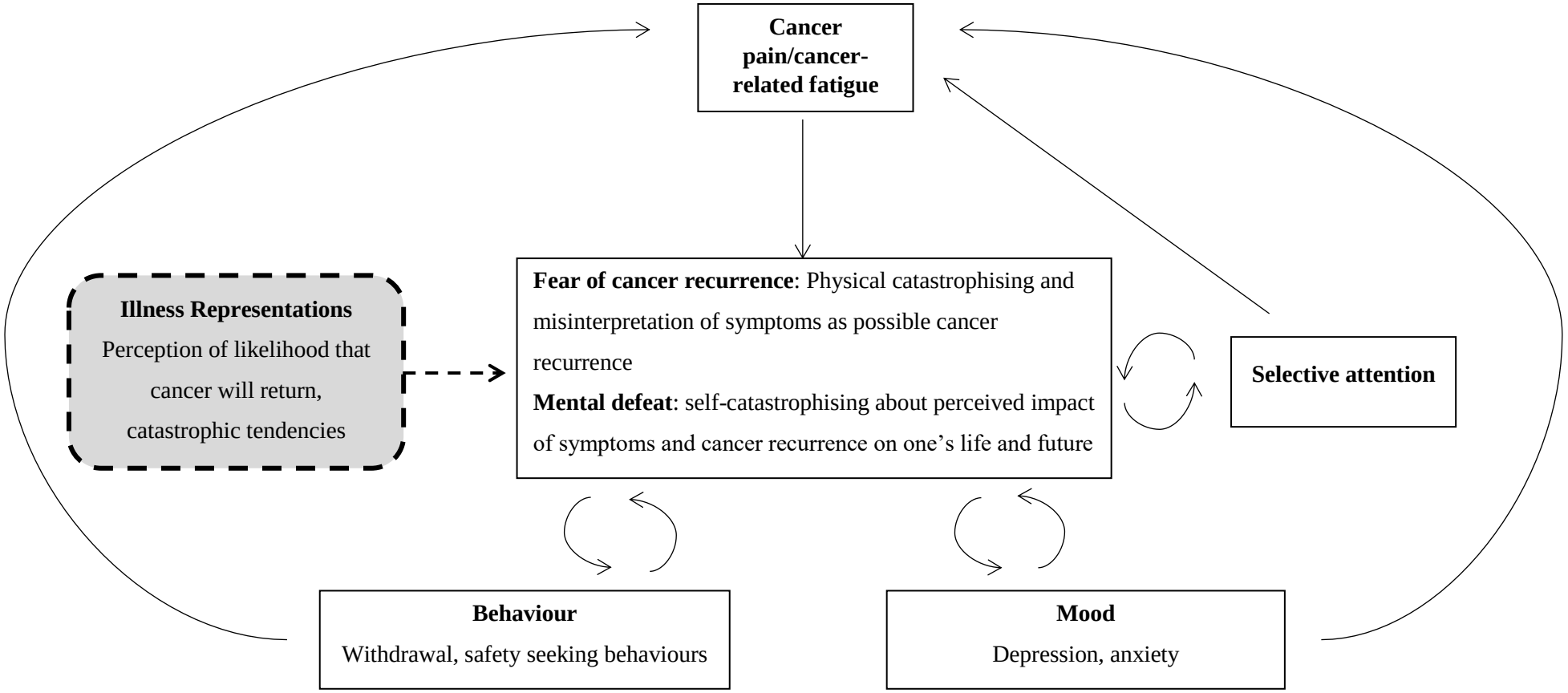


Figure 3.1 Diagrammatic representation indicating the hypothesised theoretical associations between the constructs of interest in the current study and the impact on quality of life and psychological distress

In summary, research on the experience of cancer survivors demonstrates that negative subjective interpretations about the cause and consequences of physical symptoms and sensations is linked to psychological distress. There is limited research investigating the presence of mental defeat amongst cancer survivors, although a recent study found that mental defeat and FCR were significant predictors of psychological distress amongst breast cancer survivors (Grozdziej, 2015). No studies to date have explored mental defeat amongst cancer survivors, in relation to physical symptoms experienced after treatment and the relationship between mental defeat and CRF. The present study aims to extend the literature by directly examining the role of mental defeat, FCR and health-related beliefs on psychological distress and quality of life, in cancer survivors who experience cancer pain and/or CRF. It is anticipated that this could elucidate cognitive factors underpinning the relationship between physical and psychological symptoms, which may have implications for designing therapeutic interventions. It had two stages: firstly, the deployment of a very brief screening tool evaluating fatigue, pain, depression and anxiety across a range of cancer survivors, then a more detailed and focused evaluation of those experiencing relatively higher fatigue and/or pain or not.

The primary aims of the study were therefore: 1) to develop and pilot an easily deployed screening tool to identify the perceived psychological and physical difficulties experienced by cancer survivors, 2) to identify cancer survivors experiencing CRF, cancer pain, both and a benchmark group experiencing neither, from the results of the screening tool, 3) to identify and compare the psychological mechanisms of these physical symptoms.

Hypotheses

Screening tool (first stage).

1. Cancer survivors experiencing pain will experience higher levels of anxiety relative to those experiencing fatigue, who are more likely to experience higher levels of depression.

Second study.

2. Individuals with CRF and cancer pain will have higher levels of psychological distress and lower levels of quality of life than those without.
3. The degree of distress and quality of life will be associated with psychological factors, including mental defeat, beliefs about fatigue and pain, health anxiety and FCR.

4. Cancer survivors experiencing cancer pain will experience higher levels of anxiety and mental defeat relative to those experiencing CRF, who are more likely to be depressed.
5. Those experiencing both cancer pain and CRF will show higher levels of anxiety, mental defeat and depression.

Method

Design

The study comprised two stages: the first involved piloting a screening tool and the second used a between-group cross-sectional questionnaire design. Ethical approval was granted by the Black Country National Research Ethics Service (NRES) Committee (IRAS 201581; Appendix J), the University of Bath (16-301; Appendix K) and three NHS R&D departments (University Hospitals Bristol NHS Foundation Trust, Royal United Hospitals Bath NHS Foundation Trust and Gloucestershire Hospitals NHS Foundation Trust; Appendix L).

Participants

Screening stage.

Participants were 117 cancer survivors recruited from online platforms, including Macmillan Voices, social media websites and online forums, and outpatient oncology clinics at: St Michael's Hospital, Bristol; Bristol Oncology and Haematology Centre (BHOC); Royal United Hospital, Bath (RUH); Cheltenham General Hospital (CGH) and Gloucestershire Macmillan Next Steps Cancer Rehabilitation.

The screening tool aimed to assess perceived psychological and physical difficulties experienced by all cancer survivors, regardless of cancer type or stage. Participants were eligible to complete the screening tool if they: (i) were aged 18 years or older and (ii) had a confirmed past or current diagnosis of cancer. Participants were excluded from completing the screening tool if they: (i) were not sufficiently fluent in English to understand the questionnaire and (ii) lacked capacity to consent (e.g. dementia, learning disability).

Second stage.

Participants were 33 cancer survivors who had completed the screening tool and met inclusion criteria for this stage: (i) were aged 18 years or older; (ii) had a past or current diagnosis of cancer (stages 0-III); (iii) had completed primary treatment with a curative intent and (iv) may still have been receiving medical follow-up care to reduce the risk of relapse e.g. hormone therapy or for cosmetic purposes. There were no set criteria regarding cancer type or time since diagnosis, as physical and psychological symptoms may persist after treatment for up to 15-20 years (Stanton et al., 2015).

Participants were excluded from this stage if they: (i) had a diagnosis of metastatic (stage IV) cancer; (ii) experienced cancer recurrence during the study duration; (iii) had a diagnosis of a pre-existing comorbid chronic pain and/or fatigue condition; (iv) were not sufficiently fluent in English to understand the questionnaires and (v) lacked capacity to consent.

Measures (Appendices M&N)

Screening tool.

A brief 5-item screening tool was developed by the research team to assess a combination of physical and psychological symptoms frequently reported by cancer survivors. The tool focused on clinical factors, such as time experienced and interference, as no other tool was available to measure these with the combination of symptoms that were of interest in the current study. Measuring interference provided an assessment of how much symptoms impacted on daily functioning and has been used as a measurement in previous relevant research (Tang et al., 2010). The symptoms measured in the screening tool included 1) pain, in any part of the body, 2) fatigue and tiredness, not relieved by resting, 3) depression and low mood, 4) general anxiety, about anything not related to health, 5) anxiety related to health and FCR.

Participants were asked to indicate how many hours in a day they were affected by each symptom and how much this interfered with daily life on a scale of 0 (“Not at all”) to 8 (“Very severely”), when present. For the item related to FCR, participants were advised they did not have to complete the question if they had a diagnosis of metastatic cancer and a checkbox was provided to allow indication of this.

It is intended that telephone diagnostic screening will be completed to provide validation of the screening tool in a random subsample of participants who rated the symptoms positively, in comparison to a sample of those who rated them negatively.

Second stage.

Demographic and clinical characteristics.

This was used to gather information about participants' age, gender, relationship status, employment status and ethnicity. With regards to clinical diagnosis, participants were asked about their type of cancer, date of initial diagnosis, time since completion of treatment and type of treatment/s received.

Beliefs about pain and fatigue.

The Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995) is a 13-item self-report scale which asks respondents to indicate the extent to which they experience the thoughts and feelings outlined on a scale of 0 ("Not at all") to 4 ("All the time"), when in pain. This gives a total score and subscale scores on rumination, magnification and helplessness. The PCS has demonstrated adequate to excellent internal consistency.

The Beliefs about Fatigue Scale (BAFS; Wilson, Salkovskis, & O'Dowd, 2015) is a 8-item self-report scale assessing unhelpful beliefs about the consequences of fatigue and activity, on a scale of 1 ("Strongly disagree") to 10 ("Strongly agree"). An initial study demonstrated it has good internal consistency but requires further testing (Wilson et al., 2015).

These scales were chosen to reflect pain and fatigue experienced by all participants, rather than focusing specifically on CRF or cancer pain due to two reasons: 1) individuals may find it challenging to disaggregate general symptoms and those related to cancer and 2) to obtain ratings from those who do not regard themselves as having CRF or cancer pain.

Fear of cancer recurrence.

The Fear of Cancer Recurrence Inventory-Severity Subscale (FCRI; Simard & Savard, 2009) is a 9-item self-report scale measuring the severity of intrusive thoughts about FCR on a scale of 0-4. Higher scores indicate greater levels of FCR, with item 5 reverse coded. It has shown good test-retest reliability and is appropriate for use with all cancer patients.

Health anxiety.

The Health Anxiety Inventory – Short Form (HAI-SF; Salkovskis, Rimes, Warwick, & Clark, 2002) is a 14-item self-report questionnaire measuring levels of health anxiety on a scale of 0-3 with higher scores indicating greater levels of health anxiety. The short version has high test-retest reliability, good internal consistency and correlates highly with the longer version.

Mental defeat.

The Pain Self Perception Scale (PSPS; Tang et al., 2007) is a 24-item measure adapted for use in this study, by placing *"because of my physical symptoms"* above statements related to a recent episode of intense physical symptoms. Scores are captured on a scale of 0 ("Not at all") to 4 ("Very strongly"), with higher scores indicating higher levels of mental defeat. It has high levels of internal consistency and test-retest reliability.

Quality of life.

The Quality of Life Index (QLI; Ferrans & Powers, 1985) measures the satisfaction and importance of various aspects of an individual's life, on a scale of 1 ("Very dissatisfied"/"Very unimportant") to 6 ("Very satisfied"/"Very important"). It has been adapted for use with various health conditions, including cancer and has good internal consistency.

Depression.

The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item self-report scale measuring the severity of depression. Scores on individual items range from 0 ("Not at all") to 3 ("Nearly every day"), with total scores of 5,10, 15 and 20 representing clinical cut-off points of mild, moderate, moderately severe and severe depression respectively.

General anxiety.

The Generalized Anxiety Disorder Questionnaire (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) is a 7-item self-report scale measuring the severity of anxiety. Scores on individual items range from 0 ("Not at all") to 3 ("Nearly every day"), with total scores of 5, 10 and 15 representing clinical cut-off points for mild, moderate and severe anxiety respectively.

Procedure

In oncology services, suitable participants were either identified by clinicians or approached by the lead researcher when attending for review appointments. Consenting participants completed the screening tool whilst waiting for their appointment and could opt-in to being contacted in the main study if they wished. Eligibility for the main study was completed by telephone with the lead researcher.

Suitable participants recruited through Macmillan Voices and other online platforms were invited to make initial contact by email. The screening tool and eligibility assessment were completed by telephone with the lead researcher. All participants who were eligible for the main study were sent a questionnaire pack by post, with an information sheet (Appendix O) and consent form (Appendix P). Participants were encouraged to contact the lead researcher or their named cancer nurse in the event of experiencing any distress when completing the questionnaire. Figure 3.2 shows the flow diagram of recruitment.

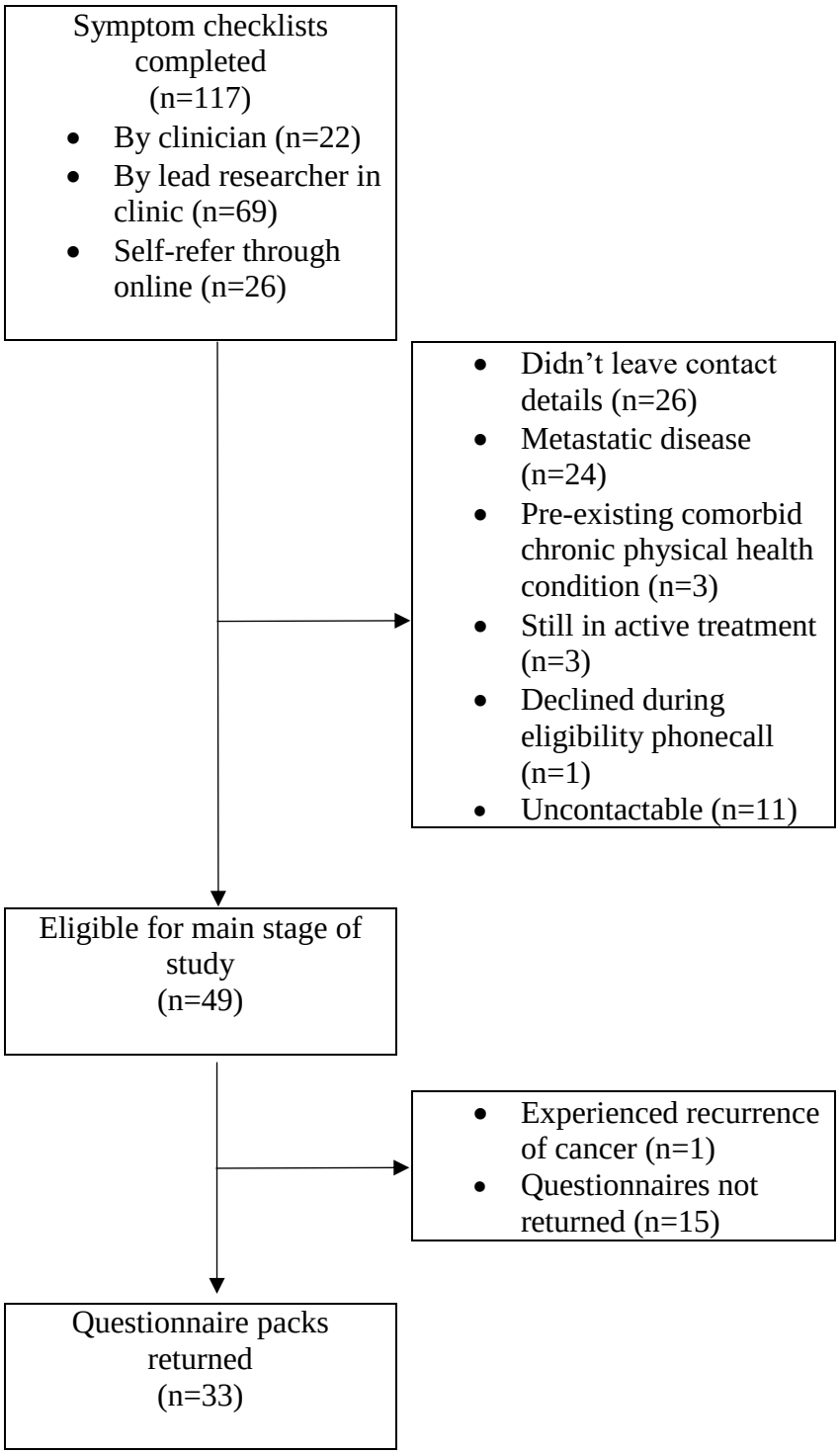


Figure 3.2 Flow diagram of recruitment

Analytic strategy

The data analytic strategy was developed *a priori* and analysis was performed using SPSS 22, with statistical significance set at $p < 0.05$. To evaluate the screening tool, interference ratings of three symptoms (pain, depression and general anxiety) were to be entered into a hierarchical multiple regression to investigate whether they could predict fatigue interference. In turn, the interference ratings of fatigue, depression and general anxiety were to be entered into a hierarchical multiple regression to investigate whether they could predict pain interference (hypothesis 1).

Cross tabulation was to be conducted to evaluate the associations between pain and fatigue interference, to help with the identification of four groups: those with both higher levels of cancer pain and CRF interference, those with higher levels of cancer pain interference only, those with higher levels of CRF interference only and those with lower levels of cancer pain and CRF interference. Higher levels of physical symptom interference were defined by the research team as a rating of ≥ 4/8 ("definitely") on the screening tool. There were insufficient participants to allow for this strategy to be used. The strategy was adapted to identify two groups: those with lower levels of both cancer pain and CRF interference (rated as ≤ 3/8 on the screening tool) and those with a higher level of either or both cancer pain and/or CRF (rated as ≥ 4/8 on the screening tool). This allowed us to compare a higher symptomatic group with a lower symptomatic group.

Independent samples t-tests were carried out to test group differences in levels of psychological distress and quality of life (hypothesis 2). Mental defeat, FCR and beliefs about fatigue and pain were entered into stepwise multiple regressions to evaluate whether they were associated with distress and quality of life respectively (hypothesis 3).

The sample size did not allow the analysis of hypotheses 4 and 5 which required the identification of four groups, however, two additional hypotheses were formulated and were analysed using stepwise multiple regression. These were to investigate whether pain, fatigue, depression and health-related anxiety interference from the screening tool could predict quality of life and FCR respectively.

Power considerations.

An *a priori* power analysis was conducted using G*Power (Faul, Erdfelder, Buchner, & Lang, 2009) to estimate the required sample size of testing hypotheses four and five of

the main part of the study with four groups. However, with a lack of comparable studies, results are tentative. A medium effect size (f^2=0.15) and power at 0.8 gave a required sample size of approximately 180 participants for analysing results with four groups (45 participants per group).

Results

Screening tool

Means and standard deviations for each symptom in the screening tool are shown in Table 3.1. By NHS recruitment site: 41% were recruited from St. Michael's Hospital, Bristol; 14% from BHOC; 13% from CGH; 6% from RUH and 4% from Gloucestershire Macmillan Next Steps Cancer Rehabilitation. 22% were recruited from online platforms.

Results found 26% (n=29) of all participants indicated experiencing no pain and fatigue (hours affected equal to zero), 18% (n=21) indicated experiencing fatigue only (hours affected equal to zero), 6% (n=7) indicated experiencing pain only and 50% (n=56) reported experiencing both pain and fatigue (hours affected greater than zero for both symptoms).

Table 3.1
Means and standard deviations of symptoms in screening tool

Variable	**Number**	**Mean**	**Standard deviation (range)**
Pain in hours (hh:mm)	114	4:14	6:54 (0:00-24:00)
Pain interference	116	2.03	2.25 (0-8)
Fatigue in hours (hh:mm)	113	4:31	6:09 (0:00-24:00)
Fatigue interference	116	3.03	2.58 (0-8)
Depression in hours (hh:mm)	110	3:05	5:48 (0:00-24:00)
Depression interference	116	2.31	2.49 (0-8)

General anxiety in hours (hh:mm)	114	2:10	3:49 (0:00-24:00)
General anxiety interference	117	2.2	2.29 (0-8)
Health-related anxiety in hours (hh:mm; excluding people with metastatic cancer)	83	3:12	5:34 (0:00-24:00)
Health-related anxiety interference (excluding people with metastatic cancer)	87	2.56	2.34 (0-8)

Regression analysis – pain and fatigue interference (hypothesis 1).

Hierarchical multiple regression analyses were performed to 1) examine the individual strength of depression, general anxiety and pain interference in predicting fatigue interference and 2) the strength of general anxiety, depression and fatigue interference in predicting pain interference. Regarding fatigue interference, in the first step depression interference contributed significantly to the regression model, accounting for 40% of the variance. The addition of general anxiety interference contributed a further 1% but this was not significant. In the third step, pain interference explained an additional 8% of the variance and this change was significant. Altogether, the variables accounted for 49% of the variance, with depression and pain interference remaining significant predictors of fatigue interference. Table 3.2 illustrates this.

Table 3.2
Hierarchical multiple regression for variables predicting fatigue interference

Model	R^2	Adjusted	F	B	β	t
Step 1						
Constant				1.431		5.516**
Depression interference	.400	.394	74.543	.658	.632	8.634**
Step 2						
Constant				1.292		4.678**
Depression interference				.582	.558	6.256**
General anxiety interference	.410	.400	2.043	.145	.128	1.429
Step 3						
Constant				.891		3.244*
Depression interference				.412	.395	4.297**
General anxiety interference				.151	.133	1.593
Pain interference	.491	.478	17.505	.377	.327	4.184**

*Note: *p<.01; **p<.001*

Regarding pain interference, in the first step general anxiety interference contributed significantly to the regression model, accounting for 7.5% of the variance. The addition of depression interference in the second step explained an additional 16.6% of the variance and this change was significant. Within this step, general anxiety interference was no longer a significant predictor. The third step resulted in fatigue interference explaining a further 10.4% of the variance which contributed significantly to the model. With all predictors in this step, general anxiety interference remained nonsignificant. All three predictors accounted for 34.5% of the variance, with fatigue interference found to be the most significant predictor of pain interference. Table 3.3 illustrates this.

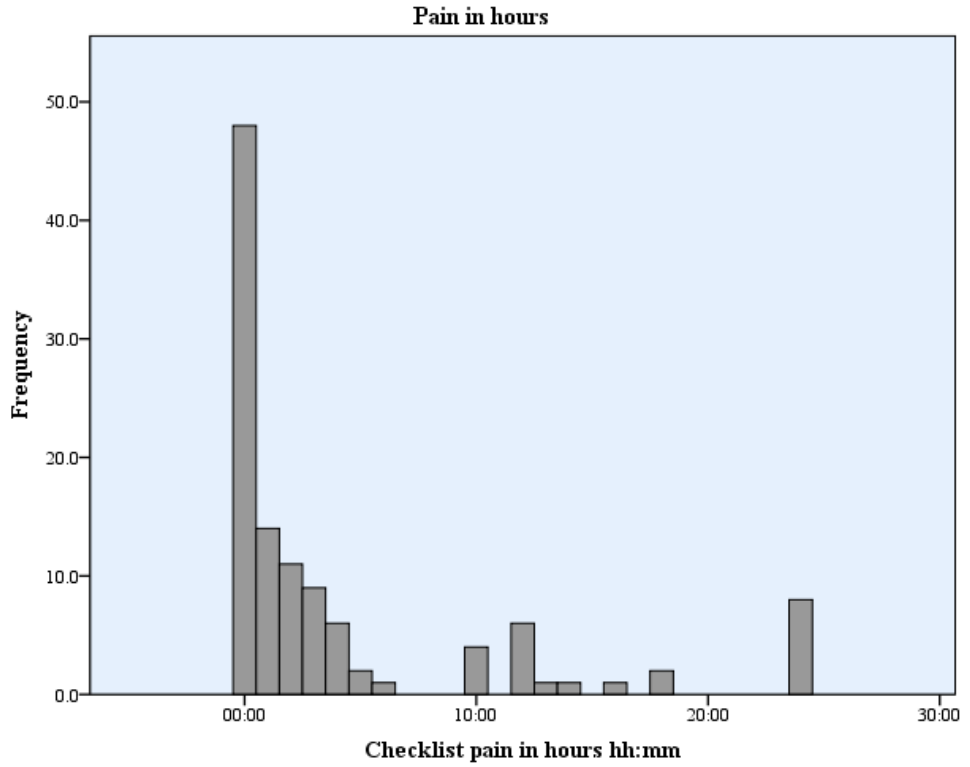
Table 3.3
Hierarchical multiple regression for variables predicting pain interference

Model	R^2	**Adjusted**	**F**	**B**	**β**	**t**
Step 1						
Constant				1.483		5.244***
General anxiety interference	.075	.066	9.024	.269	.273	3.004**
Step 2						
Constant				1.061		3.913***
General anxiety interference				-.015	-.016	-.154
Depression interference	.241	.227	24.366	.450	.500	4.936***
Step 3						
Constant				.591		2.135*
General anxiety interference				-.068	-.069	-.726
Depression interference				.239	.265	2.413*
Fatigue interference	.345	.327	17.505	.364	.420	.4.184***

*Note: *p<.05; **p<.01; ***p<.001*

Distribution of pain and fatigue (hours and interference).

Figures 3.3 and 3.4 show pain in hours and interference and fatigue in hours and interference respectively.



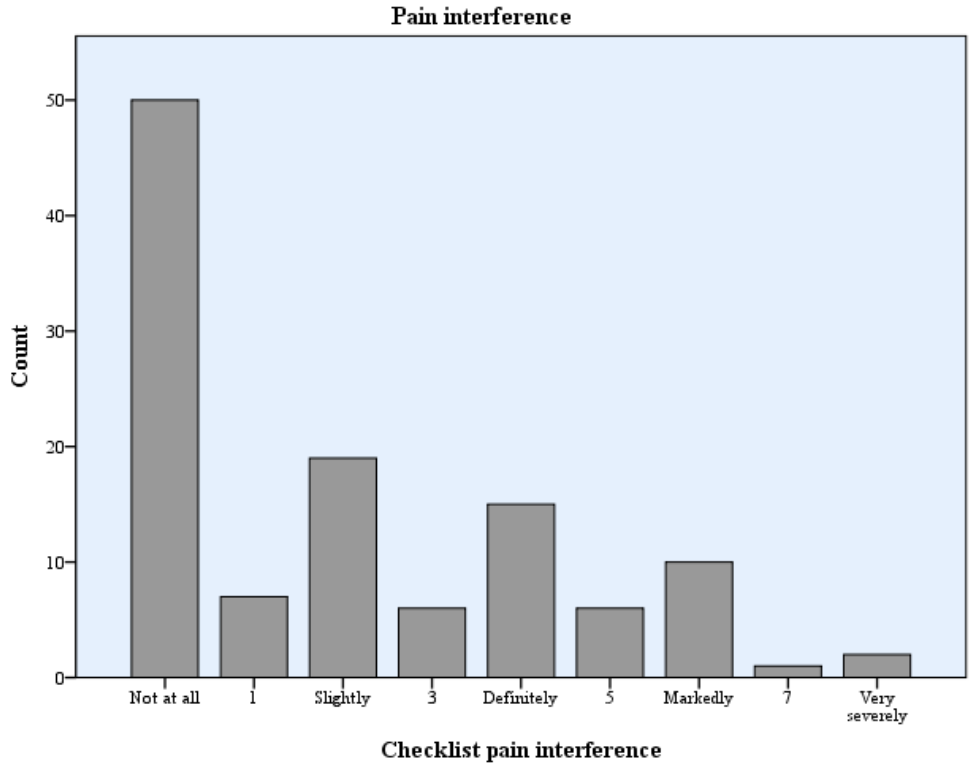
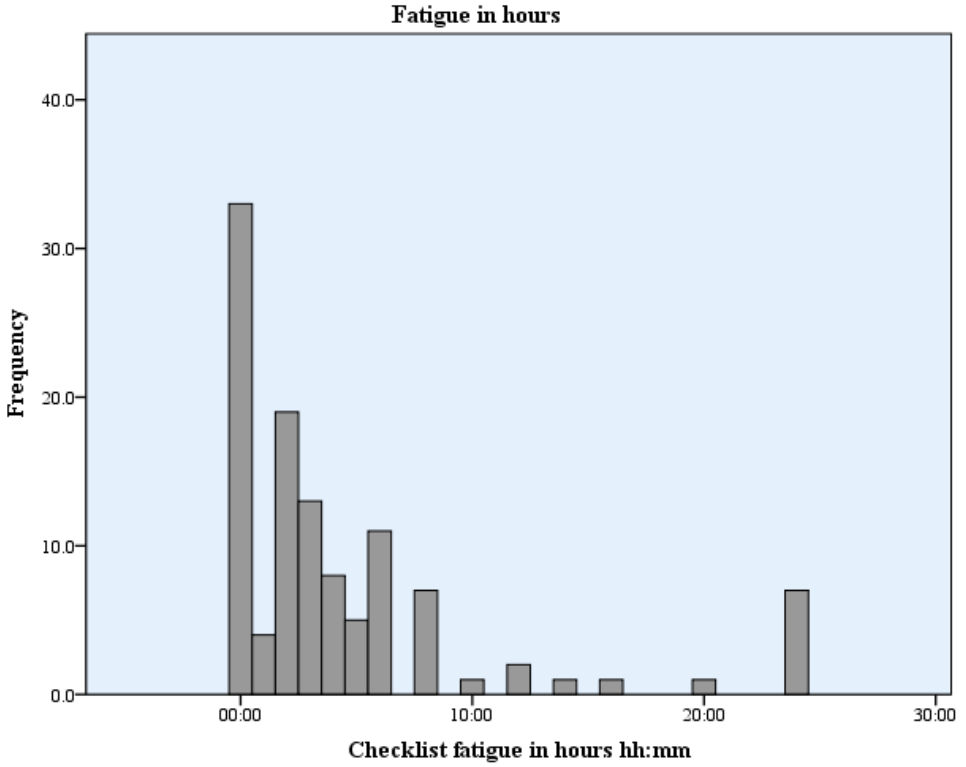


Figure 3.3 Pain in hours and pain interference distribution



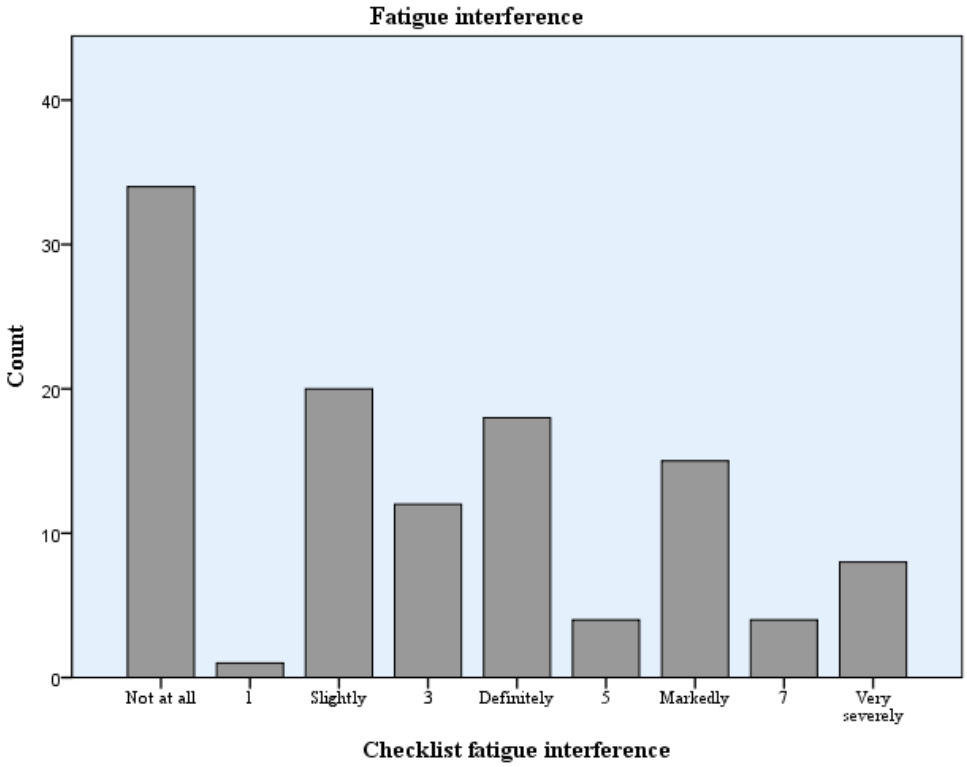


Figure 3.4 Fatigue in hours and fatigue interference distribution

Study 2: Second stage

Demographic and clinical characteristics of participants in this stage are shown in Table 3.4. Participants did not significantly differ on these characteristics. Means and standard deviations of demographic and clinical characteristics is shown in Table 3.5.

Table 3.4
Demographic and clinical characteristics of participants

Variable	**Lower levels of pain and fatigue number (%) (n=14)**	**Higher levels of pain and/or fatigue number (%) (n=19)**
Gender		
Female	13 (93)	17 (89.5)
Male	1 (7)	2 (10.5)
Ethnicity		
White British	14 (100)	15 (78.96)
White American	-	1 (5.26)
White Black Caribbean	-	1 (5.26)
Asian	-	1 (5.26)
Latin American	-	1 (5.26)
Employment status		
Employed (full-time)	4 (29)	7 (36.7)
Employed (part-time)	3 (21)	1 (5.3)
Employed (self)	1 (7)	2 (10.5)
Current sick leave	1 (7)	2 (10.5)
Student	-	1 (5.3)
Homemaker	1 (7)	1 (5.3)
Volunteer	-	1 (5.3)
Retired	1 (7)	4 (21.1)
Relationship status		
Single	-	3 (16.7)
In a relationship	2 (15)	1 (5.6)
Cohabiting	1 (8)	1 (5.6)
Engaged	1 (8)	-
Married/Civil Partnership	6 (46)	11 (61.1)
Separated	1 (8)	-
Divorced	1 (8)	2 (11)
Widowed	1 (8)	-
Cancer type		
Anal	1 (7.14)	-
Blood	1 (7.14)	-
Breast	9 (64.3)	13 (68.42)
Cervical	1 (7.14)	2 (10.54)
Lung	-	1 (5.26)
Ovarian	-	1 (5.26)
Skin	1 (7.14)	-
Thyroid	-	1 (5.26)
Vulval	1 (7.14)	-
Womb	-	1 (5.26)

Type of treatment received		
Surgery	13 (93)	18 (94.7)
Chemotherapy	7 (50)	15 (78.9)
Radiotherapy	8 (57)	14 (73.7)
Hormone therapy	5 (36)	7 (36.8)
Biological therapies	-	1 (5.3)
Time since diagnosis		
0-1 years	4 (28.6)	5 (26.32)
1-2 years	2 (14.29)	6 (31.58)
2-3 years	3 (21.43)	3 (15.79)
3-4 years	1 (7.1)	2 (10.53)
4-5 years	-	1 (5.26)
6-7 years	2 (14.29)	-
7-8 years	-	1 (5.26)
9-10 years	2 (14.29)	-
17-18 years	-	1 (5.26)
Time since last treatment		
0-1 years	7 (53.84)	8 (42.11)
1-2 years	2 (15.38)	6 (31.58)
2-3 years	2 (15.38)	2 (10.53)
3-4 years	-	1 (5.26)
5-6 years	1 (7.7)	-
7-8 years	-	1 (5.26)
8-9 years	1 (7.7)	-
17-18 years	-	1 (5.26)

Table 3.5
Means and standard deviations of demographic and clinical information

Variable	**Lower levels of pain and fatigue mean (SD) (n=14)**	**Higher levels of pain and/or fatigue mean (SD) (n=19)**
Age	56.79 (14.1)	50.42 (11.74)
Years spent in education since age 5	14.46 (3.09)	15.91 (4.35)
Time since diagnosis (months)	41.5 (37.63)	37.11 (47.7)
Time since completion of treatment (months)	23.77 (29.76)	28.68 (46.77)
Depression	4.93 (5.11)	10.32 (6.34)
Anxiety	3.71 (4.16)	8.74 (6.41)

Quality of Life	208.46 (17.86)	185.32 (34.18)
Pain Catastrophising	12.21 (9.16)	19.44 (16.03)
Beliefs about fatigue	25.07 (10.31)	34.21 (8.93)
FCR	20.15 (7.55)	21.42 (8.06)
Mental Defeat	42.79 (23.56)	57.76 (29.21)
Health Anxiety	28.36 (8.98)	31.79 (8.44)

Comparisons between lower levels of pain and fatigue interference group and higher levels of pain and/or fatigue interference group (hypothesis 2).

Independent samples t-tests were conducted (equal variances assumed) to compare those with lower levels of pain and fatigue interference and those with higher levels of pain and/or fatigue interference, on the measures of depression, anxiety, quality of life, health anxiety, FCR, mental defeat, pain catastrophising and beliefs about fatigue. Results for the primary outcomes (depression, anxiety and quality of life) indicated that those with higher levels of pain and/or fatigue interference had higher levels of depression ($t(31)=-2.612$, $p<.05$) and anxiety ($t(31)=-2.556$, $p<.05$) and lower levels of quality of life ($t(30)=2.234$, $p<.05$). There were no significant group differences on any of the other measures.

Due to the non-normal distribution of the data, non-parametric tests (Mann Whitney U) were also conducted. Results showed the same significant findings that those with higher levels of pain and/or fatigue interference had higher levels of depression ($U=62$, $p<.01$) and anxiety ($U=70$, $p<.025$) and lower levels of quality of life ($U=59$, $p<.025$).

Regression analysis – psychological distress and quality of life (hypothesis 3).

As the secondary analysis, stepwise multiple regression analyses were performed to examine the individual strength of mental defeat, FCR, beliefs about fatigue and pain catastrophising in predicting 1) depression and 2) anxiety. Regarding depression, the only variable to enter was mental defeat, accounting for 59.6% of the variance. Table 3.6 illustrates this. Regarding anxiety, the first variable to enter was mental defeat, accounting for 72.9% of the variance. The second variable to enter was FCR, accounting for an additional 4.9%. Table 3.7 illustrates this.

Table 3.6
Stepwise multiple regression for variables predicting depression

Model	R^2	Adjusted	F	B	β	t
Step 1						
Constant				-.992		-.603
Mental defeat	.596	.582	41.371	.181	.772	6.432*

*Note: *p<.001*

Table 3.7
Stepwise multiple regression for variables predicting anxiety

Model	R^2	Adjusted	F	B	β	t
Step 1						
Constant				-2.859		-2.258*
Mental defeat	.729	.720	75.461	.188	.854	8.687***
Step 2						
Constant				-5.415		-3.453**
Mental defeat				.154	.700	6.335***
Mental defeat + FCR	.778	.762	5.953	.205	.270	2.440*

*Note: *p<.05, **p<.01, ***p<.001*

A stepwise multiple regression analysis was performed to examine the individual strength of mental defeat, FCR, beliefs about fatigue and pain catastrophising in predicting quality of life. Mental defeat was the only variable to enter, accounting for 70% of the variance. Table 3.8 illustrates this.

Table 3.8
Stepwise multiple regression for variables predicting quality of life

Model	R^2	Adjusted	F	B	β	t
Constant				244.367		35.369*
Mental defeat	.702	.691	65.997	-.960	.838	-8.124*

*Note: *p<.001*

Regression analysis – symptoms from screening tool in predicting quality of life and FCR.

As an additional analysis, stepwise multiple regression analyses were performed to examine the individual strength of pain, fatigue, depression and health-related anxiety interference, as measured at screening, in predicting quality of life and FCR respectively. Regarding quality of life, a significant model accounting for approximately 55% of the variance was found. Depression interference was the strongest predictor of quality of life scores, followed by fatigue interference. Table 3.9 illustrates this.

Table 3.9
Stepwise multiple regression for screening tool variables predicting quality of life

Model	***R²***	**Adjusted**	**F**	**B**	**β**	**t**
Step 1						
Constant				218.069		34.391****
Depression interference	.448	.429	23.542	-7.668	-.669	-4.852****
Step 2						
Constant				225.192		34.375****
Depression interference				-5.171	-.451	-2.897**
Depression interference + fatigue interference	.545	.512	5.931	-4.820	1.979	-2.435*

*Note: *p<.05, **p<.01, ***p<.001, ****p<.0001*

With regards to FCR, health-related anxiety interference was the only variable to enter, accounting for 38% of the variance. Table 3.10 illustrates this.

Table 3.10
Stepwise multiple regression for screening tool variables predicting FCR

Model	***R²***	**Adjusted**	**F**	**B**	**β**	**t**
Constant				15.580		9.267*
Health-related anxiety interference	.381	.360	17.880	1.832	.433	4.228*

*Note: *p<.0001*

Discussion

This study was conducted to examine the psychological mechanisms which may be involved in cancer pain and CRF experienced by cancer survivors, in order to evaluate the impact these may have on psychological distress and quality of life. Psychological mechanisms considered included mental defeat, FCR and health-related beliefs. The screening tool was found to be applicable and effective at identifying the range of physical symptoms and psychological distress known to be present amongst many cancer survivors. Additionally, ratings of depression and fatigue interference were found to prospectively predict the outcome of quality of life in the second study, whilst health-related anxiety interference prospectively predicted FCR.

In the second study, participants identified at screening as experiencing higher levels of interference from cancer pain and/or CRF were found to have significantly higher levels of psychological distress and poorer quality of life, relative to participants with lower levels of interference from cancer pain and CRF. This finding highlights the detrimental impact the experience of physical symptoms can have on cancer survivors. These results are consistent with previous research conducted into the effect of cancer-related pain and fatigue on levels of depression, anxiety and quality of life (Brown & Kroenke, 2009; Hofman et al., 2007; Syrjala et al., 2014; Wu & Harden, 2015). For those in the current study with higher levels of cancer pain and/or CRF interference, the range of time since completion of treatment was from one month up to 18 years with a mean of approximately two years (29 months). Research suggests that symptoms experienced by cancer survivorship may reduce or resolve within the first five years post-treatment, however there are a minority who continue to experience long-term effects (Stanton et al., 2015) and current results are suggestive of this.

There were no significant group differences between those with higher levels of interference from cancer pain and/or CRF and those with lower levels of interference from cancer pain and CRF on measures of mental defeat, FCR or health-related beliefs. This finding did not support the hypothesised associations between the experience of physical symptoms and physical and self-catastrophising. Mental defeat was however, found to be a significant predictor of psychological distress and quality of life, accounting for 60-73% of the variance within these items. This high correlation between mental defeat, depression, anxiety and quality of life indicates the important role mental defeat may play in affecting psychological adjustment after cancer diagnosis and treatment.

These results are consistent with other studies investigating the role of mental defeat in cancer survivors (Grozdziej, 2015). A better understanding of the impact of cancer on survivors' sense of self and agency may be timely.

The finding that there were no group differences in levels of FCR experienced is in contrast to several studies that have found the presence of physical symptoms such as fatigue and pain to be predictive of elevated levels of FCR (Simard et al., 2013). Interestingly, the means of FCR across all participants within the current study (20-21) indicated a level which would be viewed as warranting clinical assessment, regardless of the presence of physical symptoms or not (Costa, Dieng, Cust, Butow, & Kasparian, 2016).

With regards to the screening tool, results found that approximately 50% of cancer survivors experienced both pain and fatigue to some degree. For all participants completing the screening tool, depression interference was a significant predictor of fatigue interference, followed by pain interference, accounting for 48% of the variance. This finding fit with the hypothesis and was in line with previous literature. Pain interference was significantly predicted by fatigue interference, followed by depression interference, accounting for 27% of the variance found. In contrast with previous literature and the hypothesis stated, general anxiety interference was not found to be a significant predictor of pain interference.

Results from the screening tool found that depression interference was a significant prospective predictor of fatigue interference and in turn, fatigue interference was the best predictor of pain interference. Additional findings demonstrated that levels of depression interference in the screening tool significantly predicted quality of life for participants who completed both stages of the study. These results suggest high rates of comorbidity between elevated levels of depression, fatigue and pain. Cancer survivorship literature has discussed the possibility that these symptoms may 'cluster' together within one individual (Fleishman, 2004). It is difficult to disentangle the causality between each of these symptoms, particularly as they each often present as a clinical symptom of the other e.g. fatigue as a symptom of depression (Bower, 2014) and pain as a symptom of chronic fatigue (Bourke et al., 2014). This suggests it may be more beneficial to consider treatment options for relieving symptoms and improving quality of life in people experiencing comorbidity in these symptoms.

Limitations and implications for future research

The sample obtained in the main part of the study is less than the *a priori* power calculation. This affected the initial data analytic strategy for the second part of the study; this had been devised to explore the role of mental defeat and FCR in different groups of people with varying levels of cancer pain, CRF, both and neither and two hypotheses related to this were not able to be tested. The present analysis was identified as a fall-back strategy in the event of recruitment problems. An increased sample size would have allowed for improved explorations of the psychological constructs proposed and the creation of additional groups would have made it possible to differentiate between the experience of pain and that of fatigue. It should also be noted that the data appeared skewed.

The cross-sectional nature of the second study limits the generalisability of results. Longitudinal designs may allow for exploration of cancer pain and CRF over time. The use of the screening tool did bring a level of increased validity, with the findings that health-related anxiety interference at screening was predictive of FCR during the second stage and that depression interference predicted quality of life. An interesting avenue of future research would be to investigate whether there is a group difference between individuals experiencing pain and fatigue within the first few months and years after the completion of treatment and those who experience increased chronicity of physical symptoms several years after.

Incorporating a screening question related to sleep disturbance may have been useful to consider the impact of pain and fatigue on this. Research suggests sleep may mediate the effect of pain on fatigue (Beck et al., 2005). The distribution of pain and fatigue in hours on the screening tool suggested there may be individuals who experience a level of interference that disrupts sleep.

In addition, the sample in the second stage was largely homogenous with regards to gender and ethnicity, which may reduce the generalisability of results. Whilst the screening tool was designed to be completed briefly, the collection of basic demographic information, such as gender, age and cancer type would have been useful. Due to the focus of this study on physical symptoms, it is possible that individuals with higher levels of pain and/or fatigue may have been more likely to participate.

Clinical implications

The current study provides evidence for higher levels of psychological distress and poorer quality of life amongst people who experience higher levels of cancer pain and/or CRF interference; this suggests focused interventions may improve quality of life. It has been found that cancer patients experiencing pain may not report this for many reasons, including not wanting to distract their oncologist and believing that nothing could be done to improve it (Syrjala et al., 2014). A brief screening tool, such as the one in the current study, could be used clinically to assess the psychological impact of symptoms and inform clinicians of patients who may require additional psychological support, beyond pharmacological treatment. An additional screening question related to mental defeat could also allow for earlier detection.

It may be beneficial for oncology psychological health services to liaise with medical teams and specialist pain and fatigue services to consider treatment pathways and options for cancer survivors experiencing these physical symptoms at a disruptive level which impacts on mood and quality of life.

Conclusion

In summary, this study suggests that people experiencing higher levels of cancer pain and/or CRF interference have higher levels of psychological distress and poorer quality of life, in comparison to people who experience lower levels of cancer pain and CRF. Mental defeat was found to be predictive of psychological distress and quality of life. The screening tool used appeared to be effective in identifying the physical and psychological symptoms experienced by many cancer survivors and was found to be useful in prospectively predicting FCR and quality of life.

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Executive Summary

Advances in cancer detection and treatment have increased survival rates, with approximately half of those diagnosed in England and Wales now surviving for at least ten years. However, this brings new difficulties as many cancer survivors experience a range of physical and emotional sequelae which can persist for months and years. Cancer-related fatigue (CRF) and cancer pain are two of the most prevalent physical symptoms experienced by cancer survivors and many people experience co-occurrence of both symptoms. The presence of these symptoms has been found to be associated with depression, anxiety and lower quality of life.

The experience of ongoing physical symptoms has been found to be related to elevated levels of 'fear of cancer recurrence' (FCR) which is the fear and worry that cancer may return or progress. Whilst a level of FCR can be adaptive, with engagement in medical follow-ups and healthy lifestyles, it can become disruptive to one's life with increased anxiety and the use of maladaptive coping behaviours (e.g. body-checking, hypervigilance to physical symptoms). For some individuals, catastrophic beliefs about physical symptoms can lead to the development of 'mental defeat.' This perceived loss of autonomy and control due to symptoms experienced, can lead to functional impairment and disability and is associated with higher levels of distress. The present study aimed to extend the literature by directly exploring the role of mental defeat, fear of cancer recurrence and health anxiety on psychological distress and quality of life, in cancer survivors who experience cancer pain and/or CRF.

The study had two stages. The first involved the use of a brief screening tool evaluating fatigue, pain, depression and anxiety. 117 cancer survivors, of all cancer types and stages, completed this stage. The second stage comprised 33 participants who had completed the screening tool and involved a more focused evaluation of those experiencing higher levels of cancer pain and/or CRF interference and those with lower levels of cancer pain and CRF interference. Questionnaires measured levels of depression, anxiety, quality of life, FCR, mental defeat and health-related beliefs.

The findings indicated that the screening tool was effective at identifying the range of physical and psychological symptoms known to be present amongst many cancer survivors and was useful in prospectively predicting quality of life and FCR. For those

completing the screening tool, depression interference was found to be a significant predictor of fatigue interference, followed by pain interference. Pain interference was significantly predicted by fatigue interference, followed by depression interference. In the second part of the study, participants identified at screening as experiencing higher levels of cancer pain and/or CRF interference were found to have significantly higher levels of psychological distress and poorer quality of life, in comparison to those with lower levels of cancer pain and CRF interference. There were no significant group differences found on measures of mental defeat, FCR or health-related beliefs. Mental defeat was however, found to be a significant predictor of psychological distress and quality of life, accounting for 60-73% of variance within these items.

Results should be viewed in light of a considerably smaller sample size within the second stage than anticipated which impacted on research questions and hypotheses that could be tested. An increased sample size would have allowed for greater exploration of the psychological constructs of mental defeat and FCR amongst cancer survivors experiencing cancer pain and CRF. With regards to future research, it could be beneficial to complete longitudinal studies to monitor the progress and interference of physical symptoms amongst cancer survivors over time. This could help to identify any difference between the experience of symptoms that persist in the early stages after treatment, in comparison to chronic symptoms that persist for years and decades. A measure of sleep disturbance may have also helped to identify its role within the experience of physical symptoms.

In relation to clinical practice, the brief screening tool was effective in identifying disruptive levels of physical and psychological symptoms and in prospectively predicting further difficulties, which suggests that it could be used clinically. As patients may find it difficult to communicate the negative impact of these symptoms, possibly for fear that nothing could be done to help, a screening tool could be useful to inform clinicians about patients who may be in need of psychological support. It could also be beneficial to include an additional screening question for mental defeat.

Additionally, the results suggested a high level of comorbidity between depression, pain and fatigue experienced by participants. Psychological health services in oncology settings could liaise with medical teams and specialist pain and fatigue services to

consider treatment pathways and options for cancer survivors experiencing levels of pain and fatigue interference that impact on distress and quality of life.

Connecting Narrative

My experience prior to training involved working within research teams which provided me with the opportunity to understand how research projects could be developed and conducted within a team. I was aware that my strengths in research lay in engaging with participants and handling the data collection element of studies. However, I was less knowledgeable about the design and analysis aspects of research and felt apprehensive about this when I began training. The experience of completing numerous research projects during the course has been incredibly challenging but I feel a sense of pride for what I have achieved so far. In this section I will reflect on the journey of completing case studies, a critical review of the literature, a service improvement project and the main research project.

Case studies

Writing a case study on each placement has been invaluable for drawing theory-practice links and learning how to evaluate clinical work. I naively thought that case studies would become easier over time but unfortunately, this has not happened. One difficulty lies in not being able to predict the course of the placement and your individual caseload over the six-month period. When attempting to meet the course and BABCP criteria for case studies, in addition to completing two single-case experimental design studies (SCED), this can become challenging when clients either don't engage or drop out of treatment. In addition, the three baseline measurements required for a SCED can become challenging to complete when observing a supervisor during an initial assessment who does not routinely use outcome measures. There can be a fine line between assertiveness and appearing disrespectful of their practice.

Case studies have encouraged me to think objectively about what a 'good outcome' looks like in clinical practice. A client can remark that they 'feel better' but this does not provide evidence of an effective intervention. I have learned that clinical tools for evaluating intervention outcomes may be formal, idiosyncratic, or qualitative and can be used therapeutically for the client and the therapist. I endeavour to take what I have learned from completing case studies into my future clinical work. I have further developed my understanding of the importance of evaluating clinical practice through the completion of a service improvement project.

Service Improvement Project (SIP)

I have always been interested in working with people with severe and enduring mental health problems and my first placement working with adults in a community mental health team provided me with the opportunity to do so. During this placement, a clinical psychologist in the team proposed a SIP to investigate the extent to which NICE guidelines for first episode psychosis were being implemented in the Early Intervention for Psychosis (EI) team, conducting both a clinical audit and interviews with staff. I attempted to seek an internal supervisor from the course team prior to submitting a proposal but was unable to do so. The proposal did not pass as it appeared more appropriate as a consultancy project than a SIP. I didn't want to disappoint the psychologist who had proposed the project so I persisted in attempting to amend the design. However, I was informed that it would not be possible to complete it as a SIP and that I should find an alternative project. By this time, the course had assigned Emma Griffith as my internal supervisor and through her connections she discovered that the dual diagnosis DBT team in Bath and North East Somerset (B&NES) were eager for a service evaluation to be completed. This fit within my interest of severe mental health problems and the DBT team were enthusiastic about the project.

I enjoyed the process of meeting with my external supervisor (a clinical psychologist in the DBT team) to consider what the service wanted to achieve from the evaluation and what was going to be valuable and useful. She left to go on maternity leave during the development of the questionnaires and interview schedules but enlisted help from another clinical psychologist within the team. Gaining AWP R&D evaluation and University of Bath psychology ethics felt relatively straightforward and data collection was completed by November 2016. Conducting the interviews was time-consuming to arrange and complete, as staff were at full capacity with limited availability and there was a shortage of room availability within the NHS setting.

I completed nine interviews, varying in length between 30-90 minutes and by this time, I was falling behind with my GANTT chart. I was advised that it may be wise to leave the qualitative analysis until after the final submission in May 2017 so that I could prioritise my main research project (MRP). However, there was a stubborn part of me that wanted to complete the qualitative analysis and demonstrate the time and effort that I had put into it. I was also concerned that the quantitative data may lack a richness of information as it had primarily been developed as an adjunct to the interviews. I liaised with Emma about

this and she suggested that I could possibly analyse a sample of interviews. My understanding after that meeting was that a sample involved analysing half of the client data and half of the team member data. I ploughed on, completing the transcription and analysis of this sample. Due to placement commitments and my interim external supervisor going on long-term sick leave, the only opportunity to present my findings to the DBT team was during a period of annual leave in April 2017. This was arranged hastily and Emma was not able to review my findings beforehand. Unfortunately, it was at this point that Emma and I realised that there had been miscommunication between us, as her understanding of analysing a sample meant either all of the client data *or* all of the team data; not a combination of both. Due to continued difficulties with my MRP, I was advised to complete the full analysis by both Emma and Paul Salkovskis to strengthen my research portfolio. Re-analysing my qualitative data with the addition of five interviews, in the month prior to submission, has been a rollercoaster as I have felt panic and fear about completing it on time. I have primarily learned the importance of communicating effectively so that everyone involved in a project can have a shared understanding of how it is progressing. I have been fortunate that both the team and clients have provided positive feedback about the findings and recommendations that I've presented and their enthusiasm from start to finish has maintained my motivation to complete a project that is meaningful for them.

Critical Review of the Literature

Staying within the area of severe mental health difficulties, I sought out Falguni Nathwani to supervise my literature review after she proposed the idea of exploring the nature and traits of non-suicidal self-injury (NSSI) during our research fair in December 2014. This captured my interest as I didn't know a lot about NSSI and wanted to explore what could make individuals more likely to choose this behaviour over a safer alternative. Falguni encouraged me to perform a preliminary search of the literature to look for studies of NSSI within different clinical presentations. From this search, I found that there was a small but developing literature base about NSSI in people with eating disorders.

Falguni left the university in May 2015 but stayed on as an external supervisor whilst Cara Davis took over as internal supervisor in October 2015. Around this time, I discovered that a whole book had been published on the topic of NSSI in eating disorders which raised uncertainty about whether I should continue with the literature review that I had started to work on. Cara was very supportive and liaised with the research team on

my behalf, which thankfully led to the conclusion that I should continue with my review, as it would be an academic journal article with a systematic search of the literature. I must admit that the literature review was the one project that got pushed to the bottom of my priority list at times, to make way for other projects that ran in accordance to the schedules of ethics committees and services. In the summer of 2016, I used extra study days to complete literature searches, however, I noticed that I was struggling to narrow down articles and was left with the prospect of reading over 50 full text-articles. During that summer, Cara informed me that she was redistributing her research supervision and would no longer be my supervisor but that Ailsa Russell (my clinical tutor) would take over this role. Ailsa reviewed my progress to date and helped me to operationalise my methodology which shaped up the review. Completing the review took a great deal of time but I enjoyed immersing myself within the literature, using quality appraisal tools to critically analyse studies and making use of a theoretical framework to synthesise the literature. This project felt like it was under my control and it was down to my own motivation to complete it. The review at times felt like a breath of fresh air in comparison to completing the main research project.

Main Research Project (MRP)

For many years, clinical health psychology has been my main area of interest, with a particular focus in oncology. My mum is a Macmillan Palliative Care Nurse and I believe that the passion she has for her work sparked my interest, which was strengthened when I worked with cancer patients after completing my undergraduate degree. Unfortunately, my Mum was diagnosed with cancer herself in 2012 but returned to work later that year after successful treatment. When I started training, I knew that I wanted to explore cancer survivorship and I approached Andrew Medley at the research fair to discuss my ideas about exploring grief and loss after cancer treatment. His passion for research in the area enthused me, however, he left the course team in early 2015, with Maria Loades taking over interim supervision, before Jo Daniels stepped in during the summer of 2015. The project design evolved dramatically during that time, with each supervisor suggesting a new idea about how I could proceed.

Reading the literature, I began to get a sense of the link between psychological difficulties and prevalent physical symptoms experienced by many cancer survivors. I submitted two proposals for this project between July – November 2015 but neither were accepted as the design was deemed not advanced enough for doctoral research. I had become

frustrated by this point and reached a low point of motivation at the end of 2015. I was advised to meet with Paul and he rapidly helped me to develop a design involving two stages; a screening tool and a questionnaire pack. The proposal was eventually passed in January 2016. On the course, the process of submitting research proposals has now been replaced with the verbal presentation of proposals to a panel. I acknowledge the challenges that there must be in developing and evolving a doctoral course but I believe that I lost about six months due to amending, submitting and waiting for the outcome of research proposals.

With regards to supervision at this stage, I was thrown into uncertainty as Jo unfortunately went on sick leave. However, Paul was willing to step in and provide supervision, in addition to my external supervisor, Sam Cole. I was offered another interim supervisor but I turned this down. I have wondered if this was foolish but at that time, I almost felt disconnected with the project due to the way it had evolved so far beyond my original idea and I think that I needed to take ownership back.

I made contact with several NHS oncology services in the area with varying success. Two clinical psychologists in two separate services wanted to focus on their own research and did not want to administer my screening tool. Other clinical psychologists I liaised were only able to provide me with access to their clients and I realised that I needed to cast the net further to contact oncologists, matrons and general managers of outpatient oncology departments. I had email correspondence and face-to-face meetings with several people in different services but without the project having ethical approval, they didn't want to commit. With that, I continued to gain IRAS and HRA ethical approval. This process was long-winded and monotonous as it felt like I was completing the same questions over and over, when I just wanted to get on with data collecting. In addition, the system changed in April 2016 and it felt as though nobody understood the changes. Attending the ethics panel meeting on my own in September 2016 was a daunting experience but the panel were good-humoured and I completed amendments quickly. I had a further wait for HRA approval but NHS R&D departments would not consider my application until they received this.

At this point, St Michael's Hospital in Bristol and Royal United Hospital in Bath, had both agreed to recruit participants. Cheltenham Royal Hospital, Bristol Haematology and Oncology Centre (BHOC) and Salisbury General Hospital were all potentially interested

but were unsure about the methodology. I had initially planned for the screening tool to be handed out by clinicians or reception staff and as it had very little exclusion criteria I anticipated that it could be administered to hundreds of patients. However, some services believed that their reception staff would not be able to do this and they queried whether clinicians would remember to hand the tool out during appointments. Whilst fine-tuning the procedure in each service, I received R&D approval from all but Salisbury General Hospital. Unfortunately, they cannot support student research unless the individual is currently working in their trust. I didn't fit this criterion and they weren't keen to offer an honorary contract but at that stage there wouldn't have been time to do this anyway.

During the period between October 2016 – January 2017, I spent most of my time repeatedly contacting services, being passed to different people within each team to get their personal approval and attending MDTs to introduce my project to whole teams. By mid-January, three services (Royal United Hospital, Cheltenham General and St Michael's) took a batch of screening tools to hand out. After meeting with Paul and Sam, we decided that I should widen recruitment to target charities, online forums and social media, which involved resubmitting my university ethics application for amendment. Once that was approved I created social media pages, paid Facebook to promote my study and completed an application to Macmillan Voices for them to advertise my project. Some online forums and charities are very protective of their users which I commend and respect, however, this resulted in them declining to promote my project as they didn't want to advertise too many student projects.

A month after delivering the batches of screening tools, my NHS service contacts were not responding to me and internet recruitment had resulted in only four participants. I persisted in contacting services and they all finally confirmed that they hadn't handed out any screening tools. I was left with the option of going into services and handing out the screening tool myself and I committed a total of five study days to this, which was difficult given that we only received one study day per week. The second stage was also time-consuming as it involved calling potential participants (it wasn't possible to review each screening tool in clinic due its fast-paced nature) to check eligibility criteria and sending a questionnaire pack out in the post. The numbers eventually began to rise but the ratio of participants eligible to complete the second stage was as I had expected, as many completing the screening tool had metastatic cancer, were still in treatment, or had no interest in participating further. I personally disliked going into the oncology clinics

to hand out screening tools as there is no privacy in waiting rooms and there were a proportion of people in every clinic who did not have a cancer diagnosis but were due to receive test results that day. Without the help of clinicians or reception staff to identify these patients, I was unable to know this in advance and I learned to adapt the way that I introduced myself to avoid upset.

I have developed a love-hate relationship with the MRP and I have been left feeling that psychological and student research, is not supported in a physical health setting. When speaking to participants, many of them felt as though they didn't receive adequate psychological support, despite the continued development of clinical health psychological services and this reminded me of why I believe it is an important area of research that can benefit many people. If I could restart this project, I would begin data collection at least 6-9 months earlier and would incorporate the help of a research assistant. I would take more time to consider how the procedure could be adapted for effective online use and would include a qualitative element, to capture the voices of cancer survivors.

Future aspirations

Despite the challenges that I've faced with supervisory changes and recruitment, I have learned a great deal from conducting research. I've gained experience of research governance from completing ethics applications and I've learned that conducting research within pressurised NHS environments requires time and commitment to establish and maintain professional relationships to gain the service cooperation with recruitment.

As I move towards qualified clinical practice, I would like to continue to be involved in research and develop further as a scientist-practitioner, contributing to the evidence base. From the completion of the research components in training, I believe that service development is a key type of research to become involved in. This is a critical time for our profession and continued service development could help to demonstrate our value and worth in the NHS. Within a team, I would like to become involved with wider research projects, as I believe that collaborating with colleagues could benefit the process of conducting original research.

Acknowledgments

First of all, I would like to thank my clinical tutor and literature review supervisor, Dr Ailsa Russell. I've felt supported by you throughout the course and I've always appreciated your kindness and suggestions when I've found aspects of the course difficult. You've encouraged me to focus on my learning needs, reflect on my experiences and work towards becoming a well-rounded clinical psychologist. I'd like to thank Professor Paul Salkovskis for stepping in to help with the design of my main research project and for then becoming my internal supervisor. I've appreciated the knowledge, experience and humour that you've brought to the project, when at times I've come to your office and thought that I should abandon it! Thank you to Dr Emma Griffith for identifying a new service improvement project when my original one didn't work out. Your encouragement and speedy email responses has been invaluable to helping me complete the project.

I would also like to thank each of my external supervisors and interim internal supervisors that I've been supported by in the past three years. I'd like to thank the B&NES DBT service for helping me to complete the service improvement project and for being so enthusiastic about it. For each of the services that helped with my main research project, I appreciate your help. To all the participants in my main research project and service improvement project, I appreciate your participation and have valued your willingness to share your experiences with me.

I'd like to thank my placement supervisors who have supported my professional and personal development: Claire McNally, Karen Graham, Dr Jo Keightley, Dr Claire Delaney, Dr Olivia Payne, Dr Jonnie Raynes and Dr Louise Horner-Baggs.

Moving to this area to begin training was terrifying because I didn't know anyone here but from the very first night that we met as a cohort prior to starting the course, I instantly realised that my decision to uproot had been the right one to make. I can't thank my cohort enough (especially carshare!) – you've become my family here and I couldn't have done this course without our endless group chats, birthday celebrations (cake), dinner clubs and yearly trips to Seaton! I look forward to keeping in contact with you all beyond the course.

I’d like to thank my Disney family (Callum, Arran, Louise, Jenna, Peths and Pettman) for always being there (even if we have all spread out across the world!), for providing constant fun and laughter and for being the best supporters anyone could ask for.

I’d like to dedicate this portfolio to my Granny and Grandad Young; both of whom I lost within the past two years. Your love for each other and our family was inspiring and I miss hearing your laughter. I’d like to thank my sister, Claire, and brother-in-law, Ben, for your constant motivation, humour and proofreading. It’s been so exciting to watch your family grow this year as you’ve become first-time parents to Finlay. His adorable smile and inquisitive facial expressions have kept me going when the final months of the course have been tough and I look forward to coming home soon to see how much he’s grown! Finally, I’d like to say a huge thank you to my Mum and Dad. You’ve always told me I could do whatever I set my mind to and you’ve supported me wholeheartedly, even if it’s taken me far away from home. I don’t think I’d have been able to accomplish anything that I have done without your unwavering love and belief in me.

Appendix A: European Eating Disorders Review Author Guidelines for Service Improvement Project

Author Guidelines

Manuscript style. All submissions, including book reviews, should be double-spaced and clearly legible.

The first page should contain the **title** of the paper, full names of all authors, the address where the work was carried out, and the full postal address including telephone, fax number and email to whom correspondence and proofs should be sent. The name(s) of any **sponsor(s)** of the research contained in the paper, along with **grant number(s)** should also be included.

The second sheet should contain an **abstract** of up to 150 words. An abstract is a concise summary of the whole paper, not just the conclusions, and is understandable without reference to the rest of the paper. It should contain no citation to other published work. Include up to five **keywords** that describe your paper for indexing purposes.

- **Research articles** reporting new research of relevance as set out in the aims and scope should not normally exceed 6000 words with no more than five tables or illustrations. They should conform to the conventional layout: title page, summary, introduction, materials and methods, results, discussion, acknowledgements and references. Each of these elements should start on a new page. Authors may not find it necessary to use all of these subdivisions, and they are listed here only as a guide.
- **Review articles** should offer a synthesis of current knowledge in a field where rapid or significant progress has been made. The text should ideally not exceed 7000 words, 50 references and 5 figures or tables.
- **Brief reports** should concisely present the essential findings of the author's work and be compromised of the following sections: Abstract, Introduction and Aims, Method, Results, Discussion, and References. Tables and/or figures should be kept to a minimum, in number and size, and only deal with key findings. In some cases authors may be asked to prepare a version of the manuscript with extra material to be included in the online version of the review (as supplementary files). Submissions in this category should not normally exceed 2500 words in length.
  Brief reports bring with them a whole host of benefits including: quick and easy submission, administration centralised and reduced and significant decrease in peer review times, first publication priority (this type of manuscript will be published in the next available issue of the journal).
- **Case Reports** The journal does not accept case reports for publication. Authors of case reports are encouraged to submit to the Wiley Open Access journal, Clinical Case Reports www.clinicalcasesjournal.com which aims to directly improve health outcomes by identifying and disseminating examples of best clinical practice.

Reference style. The APA system of citing sources indicates the author's last name and the date, in parentheses, within the text of the paper.

A. A typical citation of an entire work consists of the author's name and the year of publication.

Example: Charlotte and Emily Bronte were polar opposites, not only in their personalities but in their sources of inspiration for writing (Taylor, 1990). Use the last name only in both first and subsequent citations, except when there is more than one author with the same last name. In that case, use the last name and the first initial.

B. If the author is named in the text, only the year is cited.

Example: According to Irene Taylor (1990), the personalities of Charlotte. . .

C. If both the name of the author and the date are used in the text, parenthetical reference is not necessary.

Example: In a 1989 article, Gould explains Darwin's most successful. . .

D. Specific citations of pages or chapters follow the year.
Example: Emily Bronte "expressed increasing hostility for the world of human relationships, whether sexual or social" (Taylor, 1988, p. 11).

E. When the reference is to a work by two authors, cite both names each time the reference appears.
Example: Sexual-selection theory often has been used to explore patters of various insect matings (Alcock & Thornhill, 1983) . . . Alcock and Thornhill (1983) also demonstrate. .

F. When the reference is to a work by three to five authors, cite all the authors the first time the reference appears. In a subsequent reference, use the first author's last name followed by *et al*. (meaning "and others").
Example: Patterns of byzantine intrigue have long plagued the internal politics of community college administration in Texas (Douglas *et al*., 1997) When the reference is to a work by six or more authors, use only the first author's name followed by *et al*. in the first and all subsequent references. The only exceptions to this rule are when some confusion might result because of similar names or the same author being cited. In that case, cite enough authors so that the distinction is clear.

G. When the reference is to a work by a corporate author, use the name of the organization as the author.
Example: Retired officers retain access to all of the university's educational and recreational facilities (Columbia University, 1987, p. 54).

H. Personal letters, telephone calls, and other material that cannot be retrieved are not listed in References but are cited in the text.
Example: Jesse Moore (telephone conversation, April 17, 1989) confirmed that the ideas.

I. Parenthetical references may mention more than one work, particularly when ideas have been summarized after drawing from several sources. Multiple citations should be arranged as follows.
Examples:

- List two or more works by the same author in order of the date of publication: (Gould, 1987, 1989)
- Differentiate works by the same author and with the same publication date by adding an identifying letter to each date: (Bloom, 1987a, 1987b)
- List works by different authors in alphabetical order by last name, and use semicolons to separate the references: (Gould, 1989; Smith, 1983; Tutwiler, 1989).

All references must be complete and accurate. Where possible the DOI for the reference should be included at the end of the reference. Online citations should include date of access. If necessary, cite unpublished or personal work in the text but do not include it in the reference list.

Appendix B: Service Improvement Project University of Bath Psychology Ethics Approval

From: psychology-ethics
Sent: 07 June 2016 16:04
To: Dawn Lindsay
Subject: Ethics 16-132

Dear Dawn Lindsay,

Reference number 16-132**: An evaluation of the dual diagnosis Dialectical Behaviour Therapy Service in Bath and North East Somerset (BaNES)**

The ethics committee have considered your application for the study above and have given it full ethical approval.

Best wishes with your research.

Dr Michael J Proulx
Chair, Psychology Research Ethics Committee

Appendix C: AWP Research and Development approval letter

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Avon and Wiltshire Mental Health Partnership AWP Trust

AWP Quality Academy
Fromeside- East Wing
Manor Road
Fishponds
BS16 2EW
0117 378 4238/ 07825 725296

Dawn Lindsay,
Clinical Psychologist in Training,
University of Bath
Email: d.lindsay@bath.ac.uk

Date: 14th March 2016

Dear Dawn Lindsay

An evaluation of the dual diagnosis Dialectical Behaviour Therapy Service in Bath and North East Somerset (BaNES)
AWP Reference: E2016.012 Lindsay

This letter is to confirm that your evaluation is now approved and also provides you with our reference number.

If you do need any further support or information, please contact us using the contact details above, quoting our reference number for your study.

The importance of disseminating all evaluation work cannot be over emphasised. It is only by sharing our learning that we can improve services across AWP. For this reason, the findings of all evaluation work should be reported to the Evaluation team via email. The team will champion the results of service evaluations, and work with evaluators to ensure those results are disseminated and acted upon, and that the results of evaluations are reflected in future service delivery. The team will also work with evaluators to produce publications for the public domain.

I very much look forward to receiving the results of your evaluation in due course.

Yours sincerely,

Janet Brandling

Appendix D: Client questionnaire (Service Improvement Project)

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

UNIVERSITY OF BATH

Bath and North East Somerset (BaNES)

Dialectical Behaviour Therapy (DBT) Service

Client Questionnaire

1. What gender do you identify with (please circle)?

Male	Female	Other

2. What is your age?

_____

3. Which modules of DBT have you completed (please circle all that apply)?

Mindfulness	Emotion Regulation	Distress Tolerance	Interpersonal Effectiveness

4. How would you rate the quality of care that you receive from the DBT service (please circle one answer)?

Very poor	Poor	Fair	Good	Very good
1	2	3	4	5

5. How satisfied were you with the information provided to you about the service and what the therapy would involve when you had your first appointment (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

6. How satisfied are you with the weekly DBT skills-based group sessions (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

7. How satisfied are you with your individual DBT therapy sessions (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

8. How helpful have the two parts of the DBT treatment been in reducing behaviours that were, or are distressing to you?

a. Weekly skills-based group sessions (please circle one answer):

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

b. Individual therapy sessions (please circle one answer):

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

9. How helpful have the two parts of the DBT treatment been in learning to cope with difficulties you are having, in a better way?

a. Weekly skills-based group sessions (please circle one answer):

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

b. Individual therapy sessions (please circle one answer):

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

10. How important have you found the relationship with your DBT therapist/s to be (please circle one answer)?

Very unimportant	Somewhat unimportant	Neither important nor unimportant	Somewhat important	Very important
1	2	3	4	5

11. How helpful have you found it to have weekly skills-based group sessions and individual therapy sessions at the same time (please circle one answer)?

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

11. How satisfied are you with the availability of your individual therapist or another staff member of the DBT team (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

12. Have you ever contacted your individual DBT therapist by telephone for support between sessions (please circle one answer)?

Yes	No

13. Overall, how satisfied are you with the service that you receive from the DBT service (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

14. If somebody you knew was in need of similar therapy, how likely would you be to recommend this service to them (please circle one answer)?

Very unlikely	Somewhat unlikely	Neither likely nor unlikely	Somewhat likely	Very likely
1	2	3	4	5

Thank you for your time

Appendix E: Client interview schedule (Service Improvement Project)

Coming into the DBT service

1. How did you first become aware of the DBT service?

2. Name up to 3 things that you hoped to achieve when you started DBT?

3. How close do you think the service has come to meeting your expectations?

4. How did you find the assessment experience?

    a. Did you feel that you had time to explore things that were concerning you?

    b. Did you feel understood? *What helped with this?*

5. What was helpful/unhelpful about the information given to you during your first appointment?

6. How could this information be improved?

Modules

7. What have you found helpful/unhelpful about each of the modules that you've completed?

8. Are there any modules that you have preferred over others *(if more than one completed)*?
    - why?

Weekly group vs individual

9. How have the weekly skills-based group sessions/individual therapy sessions helped/not helped in reducing distressing behaviours?
    - *Has one been more helpful than the other?*

10. How have the weekly skills-based group sessions/individual therapy sessions helped/not helped in learning to cope with difficulties?
    - *Has one been more helpful than the other?*
11. Is there anything else that is particularly helpful/unhelpful about the weekly skills-based group sessions?

12. How could they be improved?

13. Is there anything else that is particularly helpful/unhelpful about your individual therapy sessions?

14. How could they be improved?

Relationship with team members

15. What do you think is the main thing that helps to build a good relationship between service users and DBT therapists?

16. If you were to give one piece of to a DBT therapist – what advice would you give them?

17. If you were to give one piece of advice to a group facilitator – what advice would you give them?

Phone consultation

18. *Yes* – What was helpful/unhelpful about it?

    No – Has there been anything that stops from calling your therapist for support between sessions? What would help you to use it more often?

General points about DBT service

19. Which parts of DBT do you prefer the most?
    (*Prompt – do they have any preference over group sessions/individual sessions?)*

20. What is helpful/unhelpful about the resources used within therapy, e.g. diary cards, measures/questionnaires/handouts?

21. How could they be improved?

22. Thinking about the DBT service as a whole can you name up to 3 ways that you think it could be improved?

23. What one piece of advice would you give to somebody who was going to start DBT?

24. Is there anything else you would like to add that we have not spoken about?

Appendix F: Team member questionnaire (Service Improvement Project)

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

UNIVERSITY OF BATH

Bath and North East Somerset (BaNES)

Dialectical Behaviour Therapy (DBT) Service

Team Member Questionnaire

1. What gender do you identify with (please circle)?

Male	Female	Other

2. What is your job title?

_____

3. How long have you been working for the DBT service?

_____

4. Which parts of the DBT service are you involved with (please circle all that apply)?

Weekly skills based group meeting	Individual therapy sessions	Phone consultation
Weekly consultation group	DBT assessments	

5. How would you rate the quality of care that is delivered by the DBT service (please circle one answer)?

Very poor	Poor	Fair	Good	Very good
1	2	3	4	5

6. How effective do you think the DBT service is in meeting the complex needs of the service users (please circle one answer)?

Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective
1	2	3	4	5

7. Overall, how satisfied do you think service users are with the DBT service (please circle one answer)?

Very unsatisfied	Somewhat unsatisfied	Neither satisfied nor unsatisfied	Somewhat satisfied	Very satisfied
1	2	3	4	5

8. How effective do you think the DBT service is at measuring change and improvement (please circle one answer)?

Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective
1	2	3	4	5

9. How helpful do you think the current outcome measures used are (please circle one answer)?

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

10. How helpful do you think the resources and materials (e.g. diary cards/handouts) currently used by service users are (please circle one answer)?

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

11. How helpful are the weekly consultation meetings (please circle one answer)?

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

12. How helpful was the DBT training that you received (please circle one answer)?

Very unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

13. How effective do you think the training was for preparing you to run weekly skills-based group sessions (please circle one answer)?

Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective
1	2	3	4	5

14. How effective do you think the training was for preparing you to deliver individual therapy sessions to service users (please circle one answer)?

Very ineffective	Somewhat ineffective	Neither effective nor ineffective	Somewhat effective	Very effective
1	2	3	4	5

Team member questionnaire
V1 May 2016

Thank you for your time

Appendix G: Team member interview schedule

Additional follow-up questions will be asked where appropriate to clarify responses
(Italics indicate prompt to interviewer)

Effectiveness and service user perspective

1. What do you think the DBT service does well in meeting the service users' needs?
2. How do you think the service could be improved to meet the needs of the service users in a more effective way?
3. What do you think service users value about the therapy they receive?
4. How do you think service users would want the DBT service to improve, if at all?

Measuring change

5. How does the DBT service currently measure change and improvement (*e.g. measures used and how often these are completed)*?
6. How do you think change and improvement could be measured in a more effective way?
7. Are there any symptoms or behaviours shown by service users that you think should be measured that aren't currently?

Consultation meetings

8. What is helpful/unhelpful about the weekly consultation meeting?
9. How do you think the consultation meetings could be improved?

DBT training

10. What was helpful/unhelpful about the DBT training and how it prepared you for delivering the service?
11. Are there any barriers to offering individual therapy sessions?
12. What do you think are the benefits of offering individual therapy sessions?

Improvements in general

13. Do you have any other suggestions about how you think the DBT service could be improved?
14. Is there anything else that you would like to add that we have not spoken about?

Appendix H: British Journal of Clinical Psychology Author Guidelines for Critical Review of the Literature

Author Guidelines

The British Journal of Clinical Psychology publishes original contributions to scientific knowledge in clinical psychology. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

All papers published in The British Journal of Clinical Psychology are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

The following types of paper are invited:
• Papers reporting original empirical investigations
• Theoretical papers, provided that these are sufficiently related to the empirical data
• Review articles which need not be exhaustive but which should give an interpretation of the state of the research in a given field and, where appropriate, identify its clinical implications
• Brief reports and comments

Length

The word limit for papers submitted for consideration to BJCP is 5000 words and any papers that are over this word limit will be returned to the authors. The word limit does not include the abstract, reference list, figures, or tables. Appendices however are included in the word limit. The Editors retain discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length. In such a case, the authors should contact the Editors before submission of the paper.

Submission and reviewing

All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submission and the declaration of competing interests. You may also like to use the Submission Checklist to help you prepare your paper.

Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. You may like to use this template. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the Project CRediTwebsite for a list of roles.
• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• All papers must include a structured abstract of up to 250 words under the headings: Objectives, Methods, Results, Conclusions. Articles which report original scientific research should also include a heading 'Design' before 'Methods'. The 'Methods' section for systematic reviews and theoretical papers should include, as a minimum, a description of the methods the author(s) used to access the literature they drew upon. That is, the abstract should summarize the databases that were consulted and the search terms that were used.

• All Articles must include Practitioner Points – these are 2–4 bullet points to detail the positive clinical implications of the work, with a further 2–4 bullet points outlining cautions or limitations of the study. They should be placed below the abstract, with the heading 'Practitioner Points'.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.
If you need more information about submitting your manuscript for publication, please email Melanie Seddon, Managing Editor (bjc@wiley.com) or phone +44 (0) 1243 770 108.

Brief reports and comments

These allow publication of research studies and theoretical, critical or review comments with an essential contribution to make. They should be limited to 2000 words, including references. The abstract should not exceed 120 words and should be structured under these headings: Objective, Method, Results, Conclusions. There should be no more than one table or figure, which should only be included if it conveys information more efficiently than the text. Title, author name and address are not included in the word limit.

Supporting Information

BJC is happy to accept articles with supporting information supplied for online only publication. This may include appendices, supplementary figures, sound files, videoclips etc. These will be posted on Wiley Online Library with the article. The print version will have a note indicating that extra material is available online. Please indicate clearly on submission which material is for online only publication. Please note that extra online only material is published as supplied by the author in the same file format and is not copyedited or typeset. Further information about this service can be found at http://authorservices.wiley.com/bauthor/suppmat.asp

Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form

upon acceptance of the paper. A copy of the Colour Work Agreement form can be downloaded here.

Appendix I: Psycho-Oncology Author Guidelines for Main Research Project

Author Guidelines

MANUSCRIPT CATEGORIES AND REQUIREMENTS

Psycho-Oncology publishes a number of different article types including:

• **Original Paper**

Original research papers should contain reports of new research findings or conceptual analyses that make a significant contribution to knowledge. Original papers should not exceed 4,000 words (including no more than four figures and/or tables) plus up to 40 references.

• **Reviews**

Reviews should be critical reviews of the literature, including systematic reviews and meta-analyses and should not exceed 6,000 words, excluding references. Please complete and supply an AMSTAR checklist for systematic reviews which are narrative reviews and not meta-analyses.

• **Editorials**

Editorials are usually invited but unsolicited material may be considered. Please approach the Editorial Office (Psycho-Oncology@wiley.com) before submitting this material. Editorials have a limit of 1,000 words.

• **Letters to the Editor**

Letters to the Editor are welcomed and should not exceed 400 words. Please note that if Letters to the Editor include a comment on a previously published paper the authors of said paper should be allowed 4 weeks in which to respond. If there is no response after 4 weeks, the Letter will simply be accepted with an Editor's footnote: "The authors of [title of previously published paper] offered no comments"

• **Book Review**

Proposal for book reviews, may be submitted to the book review Editor, Errol Philip (ejphilip@gmail.com)

• **Clinical Correspondence**

Clinical Correspondence may include feasibility studies, case studies, phase I/II clinical trials, questionnaire development studies, service development, commentary and novel clinical techniques. They must include five succinct key points (and no abstract), not exceed 1,500 words (including no more than two figures and/or tables), excluding reference. They should also be limited to ten references maximum.

• **Invited Perspective**

Invited perspectives are opinion pieces written by select individuals within the field on certain topics. They are usually invited by the Editors.

• **Invited Commentary**

Commentaries are usually written by an expert investigator who is invited by the Editors. They are usually written in response to a previously published article or Editorial.

Qualitative manuscript submissions should usually be based on a minimum of 20 respondents. Authors may contact the Editors (hollandj@mskcc.org; maggie.watson@live.co.uk) if they require further details.

PREPARING YOUR SUBMISSION

Manuscripts must be submitted as a Word or rtf file and should be written in English. The manuscript should be submitted in separate files: main text file; figures.

Text file
The text file should be presented in the following order:

(i) Title; (ii) a short running title of less than 70 characters; (iii) the full names of the authors; (iv) the author's institutional affiliations at which the work was carried out, (footnote for author's present address if different to where the work was carried out); (v) abstract; (vi) main text, (vii) acknowledgements, (viii) conflict of interest statement, (ix) references, (x) tables (each table complete with title and footnotes) (xi) figure legends, (xii) appendices (if relevant). Figures and supporting information should be supplied as separate files.

Title
The title should be a short informative title that contains the major key words. The title should not contain abbreviations (see Wiley's best practice SEO tips)

Authorship
Please refer to the journal's authorship policy the Editorial Policies and Ethical Considerations section for details on eligibility for author listing.

Acknowledgements
Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

Conflict of Interest Statement
You will be asked to disclose conflicts of interest during the submission process. See the section 'Conflict of Interest' in the Editorial Policies and Ethical Considerations section for details on what to include in this section. Please ensure that you liaise with all co-authors to confirm agreement with the final statement. The Conflict of Interest statement should be included within the main text file of your submission.

Abstract
Please provide an abstract of no more than 250 words. Abstracts should be structured according to the following headings: objective, methods, results, conclusions.

Keywords
Please provide up to 10 keywords and list them in alphabetical order. Please ensure that the keywords, cancer and oncology, are used for indexing purposes. Keywords should be taken from those recommended by the US National Library of Medicine's Medical Subject Headings (MeSH) browser list at https://www.nlm.nih.gov/mesh/.

Main text
Where possible, the text should be divided into the following sections: Background, Methods (including statistical methods), Results and Conclusions. All papers must include within the Conclusions section a paragraph explaining the study limitations (with subtitle "study limitations") and a paragraph explaining the clinical implications of the study (with subtitle "clinical implications").

A statement explicitly describing the ethical background to this study and any institutional or national ethical committee approval (including approval number) must be included within the manuscript.

For clinical trial reports, the clinical trial registration number must be included within the manuscript.

References

All references should be numbered consecutively in order of appearance and should be as complete as possible. In text citations should be superscript numbers. Journal titles are abbreviated; abbreviations may be found in the following: MEDLINE, Index Medicus, or CalTech Library.
Submissions are not required to reflect the precise reference formatting of the journal (use of italics, bold etc.), however it is important that all key elements of each reference are included. Please see below for examples of reference content requirements.

For more information, please see the Vancouver Reference Style Guide
Sample references follow:

Journal Article
1. Wood WG, Eckert GP, Igbavboa U, Muller WE. Statins and neuroprotection: a prescription to move the field forward. Ann N Y Acad Sci 2010; 1199:69-76.

Book
2. Hoppert, M. Microscopic techniques in biotechnology. Weinheim: Wiley-VCH; 2003.

Electronic Material
3. Cancer-Pain.org [homepage on the internet]. New York: Association of Cancer Online Resources, Inc.; c2000–01 [Cited 2015 May 11]. Available from: http://www.cancer-pain.org/.

Tables
Tables should be self-contained and complement, but not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figure Legends
Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Preparing Figures
Although we encourage authors to send us the highest-quality figures possible, for peer-review purposes we are happy to accept a wide variety of formats, sizes, and resolutions.

Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Guidelines for Cover Submissions
If you would like to send suggestions for artwork related to your manuscript to be considered to appear on the cover of the journal, please follow these general guidelines.

Appendices
Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text. Supporting Information

Supporting Information
Supporting information is information that is not essential to the article but that provides greater depth and background. It is hosted online, and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc. Click here for Wiley's FAQs on supporting information.
Note, if data, scripts or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points
The following links provide general advice on formatting and style.

• Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
• Units of measurement: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website at http://www.bipm.fr for more information about SI units.
• Trade Names: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name, and the name and location of the manufacturer, in parentheses.

Data storage and documentation
Psycho-Oncology encourages data sharing wherever possible, unless this is prevented by ethical, privacy or confidentiality matters. Authors publishing in the journal are therefore encouraged to make their data, scripts and other artefacts used to generate the analyses presented in the paper available via a publicly available data repository, however this is not mandatory. If the study includes original data, at least one author must confirm that he or she had full access to all the data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Ethics
A statement explicitly describing the ethical background to this study and any institutional or national ethical committee approval must be included within the manuscript.

Human Studies and Subjects

For manuscripts reporting medical studies involving human participants, we require a statement identifying the ethics committee that approved the study, and that the study conforms to recognized standards, for example: Declaration of Helsinki; US Federal Policy for the Protection of Human Subjects; or European Medicines Agency Guidelines for Good Clinical Practice.

Images and information from individual participants will only be published where the authors have obtained the individual's free prior informed consent. Authors do not need to provide a copy of the consent form to the publisher, however in signing the author license to publish authors are required to confirm that consent has been obtained. Wiley has a standard patient consent form available.

Conflict of Interest

Psycho-Oncology requires that all authors disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or directly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include, but are not limited to, patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. The existence of a conflict of interest does not preclude publication. If the authors have no conflict of interest to declare, they must also state this at submission. It is the responsibility of the corresponding author to review this policy with all authors and collectively to disclose with the submission ALL pertinent commercial and other relationships. The Conflict of Interest statement should be included within the main text file of your submission.

Funding

Authors should list all funding sources in the Acknowledgments section. Authors are responsible for the accuracy of their funder designation. If in doubt, please check the Open Funder Registry for the correct nomenclature: http://www.crossref.org/fundingdata/registry.html

Authorship

The list of authors should accurately illustrate who contributed to the work and how. All those listed as authors should qualify for authorship according to the following criteria:

1) Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

2) Been involved in drafting the manuscript or revising it critically for important intellectual content;

3) Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and

4) Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section (for example, to recognize contributions from people who provided technical help, collation of data, writing assistance, acquisition of funding, or a department chairperson who provided general support). Prior to submitting the article all authors should agree on the order in which their names will be listed in the manuscript.

Additional authorship options

Joint first or senior authorship: In the case of joint first authorship a footnote should be added to the author listing, e.g. ‘X and Y should be considered joint first author’ or ‘X and Y should be considered joint senior author.’

Appendix J: HRA and IRAS ethics approval letters with amendments

HRA Approval Letter

NHS
Health Research Authority

Miss Dawn Lindsay
Clinical Psychologist in Training
Email: hra.approval@nhs.net

Taunton and Somerset NHS Foundation Trust
Trainee Base, 10W, Clinical Psychology Department
University of Bath, Claverton Down
Bath
BA2 7AY

22 November 2016

Dear Miss Lindsay

Letter of HRA Approval

Study title:	**Exploring the role of mental defeat, fear of cancer recurrence, and health related beliefs in distress and quality of life amongst cancer survivors experiencing persistent pain and fatigue**
IRAS project ID:	**201581**
REC reference:	**16/WM/0420**
Sponsor	**University of Bath**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities

- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.

- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **201581**. Please quote this on all correspondence.

Yours sincerely

Alison Thorpe

Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Professor Jonathan Knight, University of Bath, Sponsor Contact*

Diana Benton, University Hospitals Bristol NHS Foundation Trust, Lead NHS R&D Contact

IRAS Approval Letter

West Midlands - Black Country Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

28 October 2016

Miss Dawn Lindsay
Clinical Psychologist in Training
Taunton and Somerset NHS Foundation Trust
Trainee Base, 10W, Clinical Psychology Department
University of Bath, Claverton Down
Bath
BA2 7AY

Dear Miss Lindsay

Study title:	**Exploring the role of mental defeat, fear of cancer recurrence, and health related beliefs in distress and quality of life amongst cancer survivors experiencing persistent pain and fatigue**
REC reference:	**16/WM/0420**
Protocol number:	**N/A**
IRAS project ID:	**201581**

Thank you for your letter of 19 October 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair together with another Committee member.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Georgia Copeland, nrescommittee.westmidlands-blackcountry@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]	1	19 October 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of University of Bath Insurance]		
IRAS Application Form [IRAS_Form_20102016]		20 October 2016
Letter from sponsor [Sponsorship approval from University of Bath]	1	18 August 2016
Letters of invitation to participant [Letter of Invitation for Stage 2]	1	23 August 2016
Non-validated questionnaire [Screening Tool (Symptom Checklist)]	1	23 August 2016
Non-validated questionnaire [Screening Tool (Symptom Checklist)]	2	12 October 2016
Non-validated questionnaire [Treatment Info for Questionnaire Pack]	2	12 October 2016
Non-validated questionnaire [Demographic Info for Questionnaire Pack]	2	18 October 2016
Participant consent form [Stage 2 Consent Form]	1	23 August 2016
Participant consent form [Stage 2 Consent Form]	1	23 August 2016
Participant information sheet (PIS) [Stage 1 Information Sheet]	2	18 October 2016
Participant information sheet (PIS) [Stage 1 Information Sheet Clean]	2-1	18 October 2016
Participant information sheet (PIS) [Stage 2 Information Sheet]	2	19 October 2016
Participant information sheet (PIS) [Stage 2 Information Sheet Clean]	2-1	19 October 2016
Research protocol or project proposal [Research Protocol]	2	12 October 2016
Summary CV for Chief Investigator (CI) [Summary CV for CI]	1	23 August 2016
Summary CV for supervisor (student research) [Summary CV for academic supervisor]	1	23 August 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay Summary]	1	23 August 2016
Validated questionnaire [Pain Catastrophizing Scale]		

Validated questionnaire [Health Anxiety Inventory Short Form]		
Validated questionnaire [Pain Self Perception Scale]		
Validated questionnaire [Quality of Life Index]		
Validated questionnaire [Patient Health Questionnaire PHQ 9]		
Validated questionnaire [Beliefs about Fatigue Symptoms]		
Validated questionnaire [Generalized Anxiety Disorder Questionnaire GAD 7]		
Validated questionnaire [Fear of Cancer Recurrence Severity Subscale]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/WM/0420 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

PP

Dr Hilary Paniagua Chair

Email:nrescommittee.westmidlands-blackcountry@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Professor Jonathan Knight*

Diana Benton, University Hospitals Bristol NHS Foundation Trust

Approval for amendment

Dear Miss Dawn Lindsay,

IRAS Project ID:	201581
Short Study Title:	Psychological factors, pain and fatigue in cancer survivors
Date complete amendment submission received:	17/01/2017
Amendment No./ Sponsor Ref:	NSA #1 - Minor change to Screening tool (Symptom Checklist)
Amendment Date:	17/01/2017
Amendment Type:	**Non-substantial**

Thank you for submitting the above referenced amendment. In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

Category C - An amendment that has no implications that require management or oversight by the participating NHS organisations

As such, the sponsor may implement this amendment **as soon as any relevant regulatory approvals are in place** (for participating organisations in England, please see 'Confirmation of Assessment Arrangements' below).

As Chief Investigator/Sponsor, it remains your responsibility to ensure that the research management offices and local research teams (if applicable) at each of your participating organisations are informed of this amendment.

Note: you may only implement changes described in the amendment notice or letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards

Alka Bhayani

HRA Approvals - Amendments Coordinator

Appendix K: University of Bath psychology ethics approval emails

Approval email

From: psychology-ethics
Sent: 08 November 2016 15:32
To: Dawn Lindsay
Subject: Ethics 16-301

Dear Dawn,

16-301: Exploring the role of mental defeat, fear of cancer recurrence and quality of life amongst cancer survivors experiencing persistent pain and fatigue

I am happy to approve this ethics application via Chair's Action, please use the code 16-301 as proof of approval.

Best of luck with your data collection,

Dr. Nathalia Gjersoe
Chair, Psychology Ethics Committee

Approval for amendment made

From: psychology-ethics
Sent: 20 January 2017 14:52
To: Dawn Lindsay
Subject: Ethics 16-301

Dear Dawn,

Thank you very much for the ethics application form and for all the attachments. I am happy to confirm that you have full ethical approval to widen your recruitment strategy as specified.

Best of luck with your data collection,
Dr. Nathalia Gjersoe
Chair, Psychology Ethics Committee

Appendix L: R&D approval emails

University Hospitals Bristol approval

Hi Dawn

Confirmation of Capacity and Capability at University Hospitals Bristol NHS Foundation Trust

IRAS ID: 201581

Full Study Title: *Exploring the role of mental defeat, fear of cancer recurrence, and health related beliefs in distress and quality of life amongst cancer survivors experiencing persistent pain and fatigue*

This email confirms that University Hospitals Bristol NHS Foundation Trust has the capacity and capability to support the above referenced study, as a Participating Identification Centre. Please find attached our agreed Statement of Activities as confirmation.

We agree to start this study on a date to be agreed when you as sponsor give the green light to begin.

Please contact the Research Management Office should you require further clarifications.

We would like to wish you all the very best with your study.

Kind regards

Catherine Down

Research Management Facilitator

Research & Innovation | University Hospitals Bristol NHS Foundation Trust | Level 3, Education and Research Centre | Upper Maudlin Street | Bristol | BS2 8AE | Tel. 0117 34 20106 | catherine.down@uhbristol.nhs.uk | http://www.uhbristol.nhs.uk/research-innovation/ | Working with the NIHR, Industry and Charities to improve patient care through high quality research

Royal United Hospital Bath approval

Dear Dawn

RE: IRAS 201581 Confirmation of Capacity and Capability at Royal United Hospitals Bath NHS Foundation Trust.

Full Study Title: Exploring the role of mental defeat, fear of cancer recurrence, and health related beliefs in distress and quality of life amongst cancer survivors experiencing persistent pain and fatigue

This email confirms that Royal United Hospitals Bath NHS Foundation Trust has the capacity and capability to deliver the above referenced study (PIC only). Please find attached the completed Statement of Activities as confirmation.

Please can you confirm by email the start and finish dates of this projects.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

Jane Carter
R&D Manager,
RNHRD site

Gloucestershire Hospitals approval

Dear Dawn,

IRAS 201581 Confirmation of Capacity and Capability at Gloucestershire Hospitals NHS Foundation Trust
RE: Exploring the role of mental defeat, fear of cancer recurrence, and health related beliefs in distress and quality of life amongst cancer survivors experiencing persistent pain and fatigue
R&D Ref: 16/092/GHT

This email acknowledges that Gloucestershire Research Support Service is able to confirm capacity and capability to deliver the above referenced study on behalf of Gloucestershire Hospitals NHS Foundation Trust.

Please do not hesitate to contact Mark Walker or myself if you have any queries about this. A formal letter of access will follow shortly.

May I take this opportunity to wish you all the best with your study.

Kind Regards

Nigel

Nigel Johnson| Research Governance Support Officer| Gloucestershire Hospitals NHS Foundation Trust/2gether NHS Foundation Trust/Gloucestershire Care Services/Gloucestershire Clinical Commissioning Group

Appendix M: Screening tool information sheet and symptom checklist

Psychological factors, pain and fatigue in cancer survivors

Participant Information Sheet

We would like to invite you to complete a symptom checklist. Before you decide, it is important for you to understand why this is being done and what it will involve. Please take time to read the following information carefully.

Why is this being done?

Many cancer survivors experience physical symptoms, including pain and fatigue. We know that feeling low about these symptoms, fearing that cancer may return in the future and worrying about health in general, are common and very normal.

We would like to find out how often people are affected by physical and psychological symptoms and how much they interfere with daily life. Information collected from this symptom checklist will help us to update figures on how often and how much these symptoms affect people and this can help health professionals to provide support.

Who can take part?

We would like to invite people who are aged 18 years or above and have received a diagnosis of cancer.

What will I have to do?

If you wish to take part then please complete the attached symptom checklist, either before or after your appointment. Once complete, please return it to reception.

What are the benefits and risks of taking part?

Although there are no direct or immediate benefits to you completing the checklist, it is anticipated that the results will help us to understand how frequent and disruptive these symptoms are.

We consider there to be minimal risk in completing the checklist. However, if you do experience distress then you may discontinue the questions at any point. We would encourage you to discuss this with your oncologist, cancer clinical nurse specialist, or another member of your healthcare team.

Will my information be kept confidential?

Yes. In accordance with the Data Protection Act of 1998, all of the information you provide will

be handled in strict confidence and will be anonymised with your name and personal information removed. The data collected will be stored securely in locked cabinets and password protected computer files and only the research team will have access to this. Data will be kept for 5 years after the close of the study and will be destroyed after.

We will analyse the data collected and hope to report our findings within academic/health related journal and present them at conferences. The findings will also contribute to Dawn Lindsay's Doctorate in Clinical Psychology. You will not be identified in any reports or publications arising from the study.

The answers you give to this checklist will not be discussed with your oncologist or any other member of your healthcare team. However, we would encourage you to discuss any upsetting or distressing symptoms with a health professional so that they can support you with this.

What happens next?

You do not have to complete this symptom checklist and your decision whether to do so will not affect your appointment, or any current or future treatment you may receive.

This symptom checklist is the first part of a project that aims to find out which psychological factors (e.g. feeling 'defeated' by physical symptoms or fearing that cancer may return in the future) have the biggest effect on mood, anxiety and quality of life. We would also like to explore whether what people think and feel is affected by the physical symptoms that they experience. This could help us to design more effective psychological therapies to support people to manage their emotional wellbeing better.

If you would be interested in finding out more about participating in the next part of this project, then please leave your contact details in the provided space at the bottom of the symptom checklist and the researcher will be in contact shortly.

Additionally, we would like to contact a few people who have completed this symptom checklist to check its accuracy. Please leave your contact details in the provided space at the bottom of the symptom checklist if you would be interested in this.

If you have any questions or concerns, please contact the primary researcher:

Dawn Lindsay

Clinical Psychologist in Training, University of Bath

10W, Department of Clinical Psychology,

Claverton Down, Bath BA2 7AY

T: 01225 385506 **Email: d.lindsay@bath.ac.uk**

M: 07922 168468

[INSERT SERVICE LOGO]
ID: [INSERT]

Date……

Symptom checklist

We are going to ask you about some physical symptoms and emotional reactions that are common in people who have had a diagnosis of cancer and have received treatment for this.

If you have completed this checklist previously, please indicate by ticking this box ☐

1. Pain

a. For how many hours in a day are you affected by pain, in any part of your body?

…….hours

b. When it is present, how much does it interfere with your daily life?

Not at all		Slightly		Definitely		Markedly		Very severely
0	1	2	3	4	5	6	7	8

2. Fatigue

a. For how many hours in a day are you affected by tiredness or fatigue, which is not helped by resting?

…….hours

b. When it is present, how much does it interfere with your daily life?

Not at all		Slightly		Definitely		Markedly		Very severely
0	1	2	3	4	5	6	7	8

3. Depression and sadness

a. For how many hours in a day are you affected by feeling down or low in mood?

…….hours

b. When it is present, how much does it interfere with your daily life?

Not at all		Slightly		Definitely		Markedly		Very severely
0	1	2	3	4	5	6	7	8

4. General anxiety and worry

a. For how many hours in a day are you affected by anxiety about anything <u>not related</u> to your health?

…….hours

b. When it is present, how much does it interfere with your daily life?

Not at all		Slightly		Definitely		Markedly		Very severely
0	1	2	3	4	5	6	7	8

5. Anxiety focusing on your future health and fear of cancer recurrence
Please indicate whether you have a diagnosis of metastatic (secondary) cancer ☐
If you ticked this box you do not have to complete questions 5a and 5b.

a. For how many hours in a day are you affected by anxiety that is focused on your future health?

…….hours

b. When it is present, how much does it interfere with your daily life?

Not at all		Slightly		Definitely		Markedly		Very severely
0	1	2	3	4	5	6	7	8

Please return your completed symptom checklist to reception

✂----------

The next stage of this project aims to find out which psychological factors have the biggest effect on mood, anxiety and quality of life, and will explore whether what people think and feel is affected by the physical symptoms that they experience.

We would like to invite people who are aged 18 years or above and:

- Have received a past diagnosis of cancer
- Have completed primary cancer treatment
- Do NOT have any existing co-morbid chronic physical health problems

If this sounds like you and you would be interested in finding out more about participating in the next part of this project, then please leave your contact details below and the researcher will be in contact shortly.

If this does **not** sound like you but you would be interested in being contacted to help us check the accuracy of this symptom checklist, then please tick the box and leave your contact details below ☐

Name: **Phone number**:

……. …….....

Address:

……

……..

Appendix N: Questionnaire pack used in second stage of study

Psychological factors, pain and fatigue in cancer survivors

QUESTIONNAIRE PACK

Once complete, please return this pack to the researcher in the pre-paid envelope

---

Background information

1. What is your age?

   _____ years

2. What gender do you identify with (please circle)?

   Male/Female/Other (please specify_____)

3. What is your ethnicity (please state)?

   _____

4. What is your employment status (please tick)?

Employed (full time)	
Employed (part time)	
Employed (self)	
Currently on sick leave	
Unemployed (Seeking work)	
Unemployed	
Benefits	
Student (Full time)	
Student (Part time)	
Homemaker	
Volunteer	
Retired	

5. How many years have you spent in education since the age of 5 (please specify)?

   _____

6. What is your relationship status (please tick)?

Single	
In a relationship	
Cohabiting	
Engaged	
Married/Civil partnership	
Separated	
Divorced	
Widowed	
Other (please specify): ----------	

Treatment information

1. When were you first diagnosed as having cancer?

   _____

2. What type of cancer were you diagnosed with?

   _____

3. What cancer treatments have you received (please tick all that apply)?

Surgery	
Radiotherapy	
Chemotherapy	
Hormone therapy	
Targeted (Biological) therapies e.g. angiogenesis inhibitors, cancer growth inhibitors, monoclonal antibodies, vaccines	
Stem cell and bone marrow treatment	
Other (please specify): ----------	

4. When did you have your last treatment session?

5. Do you currently take any medication(s) (please tick)?

   On prescription

   ☐ Yes ☐ No

   'Over the counter'

   ☐ Yes ☐ No

   If Yes, please give the name(s) of the medication(s) below:

PHQ-9

(Kroenke, Spitzer & Williams 2001)

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	**Several Days**	**More than half the days**	**Nearly every day**
Little interest or pleasure in doing things.	0	1	2	3
Feeling down, depressed, or hopeless.	0	1	2	3
Trouble falling or staying asleep, or sleeping too much.	0	1	2	3
Feeling tired or having little energy.	0	1	2	3
Poor appetite or overeating.	0	1	2	3
Feeling bad about yourself, or that you are a failure, or have let yourself or your family down.	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
Moving or speaking so slowly that other people could have noticed? Or the opposite being so fidgety or restless that you have been moving around a lot more than usual.	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself in some way.	0	1	2	3

GAD 7

(Spitzer, Kroenke, Williams & Lowe 2006)

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	**Several Days**	**More than half the days**	**Nearly every day**
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Worrying too much about different things	0	1	2	3
Trouble relaxing	0	1	2	3
Being so restless that it is hard to sit still	0	1	2	3
Becoming easily annoyed or irritable	0	1	2	3
Feeling afraid as if something awful might happen	0	1	2	3

Short HAI

(Salkovskis, Rimes, Warwick, & Clark, 2002)

These questions relate to worries about your physical health. Each question consists of a group of four statements. Please read each group of statements carefully, then select the one which best describes your feelings over the **past six months.** Identify the statement by circling the letter next to it.

1	**A**	I do not worry about my health
	B	I occasionally worry about my health
	C	I spend much of my time worrying about my health
	D	I spend most of my time worrying about my health

2	**A**	I notice aches/pains less than most other people (of my age)
	B	I notice aches/pains as much as most other people (of my age)
	C	I notice aches/pains more than most other people (of my age)
	D	I am aware of aches/pains in my body all the time

3	**A**	As a rule, I am not aware of bodily sensations or changes
	B	Sometimes I am aware of bodily sensations or changes
	C	I am often aware of bodily sensations or changes
	D	I am constantly aware of bodily sensations or changes

4	**A**	Resisting thoughts of illness is never a problem
	B	Most of the time I can resist thoughts of illness
	C	I try to resist thoughts of illness but am often unable to do so
	D	Thoughts of illness are so strong that I no longer even try to resist them

5	**A**	As a rule I am not afraid that I have a serious illness
	B	I am sometimes afraid that I have a serious illness
	C	I am often afraid that I have a serious illness
	D	I am always afraid that I have a serious illness

6	**A**	I do not have images (mental pictures) of myself being ill
	B	I occasionally have images of myself being ill
	C	I frequently have images of myself being ill
	D	I constantly have images of myself being ill

7	**A**	I do not have any difficulty taking my mind off thoughts about my health
	B	I sometimes have difficulty taking my mind off thoughts about my health
	C	I often have difficulty in taking my mind off thoughts about my health
	D	Nothing can take my mind off thoughts about my health

8	**A**	I am lastingly relieved if my doctor tells me there is nothing wrong
	B	I am initially relieved but the worries sometimes return later
	C	I am initially relieved but the worries always return later
	D	I am not relieved if my doctor tells me there is nothing wrong

9	**A**	If I hear about an illness I never think I have it myself
	B	If I hear about an illness I sometimes think I have it myself
	C	If I hear about an illness I often think I have it myself
	D	If I hear about an illness I always think I have it myself

10	**A**	If I have a bodily sensation or change I rarely wonder what it means
	B	If I have a bodily sensation or change I often wonder what it means
	C	If I have a bodily sensation or change I always wonder what it means
	D	If I have a bodily sensation or change I must know what it means

11	**A**	I usually feel at very low risk for developing a serious illness
	B	I usually feel at fairly low risk for developing a serious illness
	C	I usually feel at moderate risk for developing a serious illness
	D	I usually feel at high risk for developing a serious illness

12	**A**	I never think I have a serious illness
	B	I sometimes think I have a serious illness
	C	I often think I have a serious illness
	D	I usually think that I am seriously ill

13	**A**	If I notice an unexplained bodily sensation I don't find it difficult to think about other things
	B	If I notice an unexplained bodily sensation I sometimes find it difficult to think about other things.
	C	If I notice an unexplained bodily sensation I often find it difficult to think about other things
	D	If I notice an unexplained bodily sensation I always find it difficult to think about other things

14	**A**	My family/friends would say I do not worry enough about my health
	B	My family/friends would say I have a normal attitude to my health
	C	My family/friends would say I worry too much about my health
	D	My family/friends would say I am a hypochondriac

Self-Perception Questionnaire

(Tang, Salkovskis & Hanna 2007)

This questionnaire includes a number of statements that describe thoughts and feelings that people sometimes experience at a time when they are experiencing physical symptoms. Please rate the extent to which these statements apply to your experience during the episode of physical symptoms by circling the appropriate number. There are no right or wrong answers to these questions. Please remember that this questionnaire is about how you felt and thought at the time of intense physical symptoms.

Because of my physical symptoms….	**Not at all**	**Very Little**	**Moderately**	**Strongly**	**Very Strongly**
1. I feel defeated by life	1	2	3	4	5
2. I feel I have lost my standing in the world	1	2	3	4	5
3. I feel that life has treated me like a punchbag	1	2	3	4	5
4. I feel powerless	1	2	3	4	5
5. I feel that my confidence has been knocked out of me	1	2	3	4	5
6. I don't feel able to deal with things that life throws at me	1	2	3	4	5
7. I feel that I have sunk to the bottom of the ladder	1	2	3	4	5
8. I feel completely knocked out of action	1	2	3	4	5
9. I feel that I am one of life's losers	1	2	3	4	5
10. I feel that I have given up	1	2	3	4	5
11. I feel down and out	1	2	3	4	5
12. I feel I have lost important battles in life	1	2	3	4	5
13. I feel that there is no fight left in me	1	2	3	4	5
14. I feel I am losing my will power	1	2	3	4	5
15. I don't care what happens to me anymore	1	2	3	4	5

16. I feel defeated	1	2	3	4	5
17. I feel less like a human being	1	2	3	4	5
18. In my mind, I give up	1	2	3	4	5
19. I feel destroyed as a person	1	2	3	4	5
20. I felt like I wanted to die	1	2	3	4	5
21. I feel like I am losing my inner resistance	1	2	3	4	5
22. I feel like an object	1	2	3	4	5
23. I feel completely at the mercy of what is happening it me	1	2	3	4	5
24. I feel humiliated and that I am losing my sense of inner dignity	1	2	3	4	5

Beliefs about Fatigue Symptoms

(Wilson, Salkovskis & O'Dowd, 2015)

We would like to know more about your beliefs about fatigue symptoms. Please indicate to what extent you personally agree or disagree with each statement by circling a number on the scale. Please circle only one box per line.

1. My fatigue problems can be caused by over-activity:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
2. It is important to avoid exercise when I feel tired:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
3. I believe that my fatigue problems are caused by a virus or infection:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
4. Doing less activity than usual helps to improve my fatigue problems:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
5. My fatigue problems can be caused by failing to get enough rest:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
6. Doing exercise is harmful to me:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
7. My fatigue problems can be caused by stress:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree
8. I should avoid doing physical activity:										
Strongly Disagree	1	2	3	4	5	6	7	8	9	10 Strongly Agree

Worrying about cancer recurrence

(Simard & Savard, 2009)

Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. **By recurrence, we mean the possibility that the cancer could return or progress in the same place or in another part of the body.** This questionnaire aims to better understand the experience of worries about cancer recurrence.

Please read each statement and indicate to what degree it applied to you **during the past month** by **circling the appropriate number**.

1. I am worried or anxious about the possibility of cancer recurrence.				
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
2. I am afraid of cancer recurrence.				
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
3. I believe it is normal to be worried or anxious about the possibility of cancer recurrence.				
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
4. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family).				
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
5. I believe that I am cured and that the cancer will not come back.				
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
6. In your opinion, are you at risk of having a cancer recurrence?				
0 Not at all at risk	1 A little at risk	2 Somewhat at risk	3 A lot at risk	4 A great deal at risk
7. How often do you think about the possibility of cancer recurrence?				
0 Never	1 A few times a month	2 A few times a week	3 A few times a day	4 Several times a day
8. How much time per day do you spend thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few seconds	2 A few minutes	3 A few hours	4 Several hours
9. How long have you been thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few weeks	2 A few months	3 A few years	4 Several years

PCS

Client No.: _____ Age: _____ Sex: M(__) F(__) Date: _____

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all **1** – to a slight degree **2** – to a moderate degree **3** – to a great degree **4** – all the time

When I'm in pain …

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.
7. ☐ I keep thinking of other painful events.
8. ☐ I anxiously want the pain to go away.
9. ☐ I can't seem to keep it out of my mind.
10. ☐ I keep thinking about how much it hurts.
11. ☐ I keep thinking about how badly I want the pain to stop.
12. ☐ There's nothing I can do to reduce the intensity of the pain.
13. ☐ I wonder whether something serious may happen.

_____

… Total

Ferrans and Powers
QUALITY OF LIFE INDEX©
CANCER VERSION - III

PART 1. For each of the following, please choose the answer that best describes how ***satisfied*** you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

How *satisfied* are you with:	**Very dissatisfied**	**Moderately dissatisfied**	**Slightly dissatisfied**	**Slightly satisfied**	**Moderately satisfied**	**Very satisfied**
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of pain that you have?	1	2	3	4	5	6
4. The amount of energy you have for everyday activities?	1	2	3	4	5	6
5. Your ability to take care of yourself without help?	1	2	3	4	5	6
6. The amount of control you have over your life?	1	2	3	4	5	6
7. Your chances of living as long as you would like?	1	2	3	4	5	6
8. Your family's health?	1	2	3	4	5	6
9. Your children?	1	2	3	4	5	6
10. Your family's happiness?	1	2	3	4	5	6
11. Your sex life?	1	2	3	4	5	6
12. Your spouse, lover, or partner?	1	2	3	4	5	6
13. Your friends?	1	2	3	4	5	6
14. The emotional support you get from your family?	1	2	3	4	5	6

15. The emotional support you get from people other than your family?	1	2	3	4	5	6
16. Your ability to take care of family responsibilities?	1	2	3	4	5	6
17. How useful you are to others?	1	2	3	4	5	6
18. The amount of worries in your life?	1	2	3	4	5	6
19. Your neighbourhood?	1	2	3	4	5	6
20. Your home, apartment, or place where you live?	1	2	3	4	5	6
21. Your job (if employed)?	1	2	3	4	5	6
22. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
23. Your education?	1	2	3	4	5	6
24. How well can you take care of your financial needs?	1	2	3	4	5	6
25. The things you do for fun?	1	2	3	4	5	6
26. Your chances for a happy future?	1	2	3	4	5	6
27. Your peace of mind?	1	2	3	4	5	6
28. Your faith in God?	1	2	3	4	5	6
29. Your achievement of personal goals?	1	2	3	4	5	6
30. Your happiness in general?	1	2	3	4	5	6
31. Your life in general?	1	2	3	4	5	6
32. Your personal appearance?	1	2	3	4	5	6
33. Yourself in general?	1	2	3	4	5	6

PART 2. For each of the following, please choose the answer that best describes how ***important*** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

How *important* to you is:	**Very unimportant**	**Moderately unimportant**	**Slightly unimportant**	**Slightly important**	**Moderately important**	**Very important**
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. Having no pain?	1	2	3	4	5	6
4. Having enough energy for everyday activities?	1	2	3	4	5	6
5. Taking care of yourself without help?	1	2	3	4	5	6
6. Having control over your life?	1	2	3	4	5	6
7. Living as long as you would like?	1	2	3	4	5	6
8. Your family's health?	1	2	3	4	5	6
9. Your children?	1	2	3	4	5	6
10. Your family's happiness?	1	2	3	4	5	6
11. Your sex life?	1	2	3	4	5	6
12. Your spouse, lover, or partner?	1	2	3	4	5	6
13. Your friends?	1	2	3	4	5	6
14. The emotional support you get from your family?	1	2	3	4	5	6
15. The emotional support you get from people other than your family?	1	2	3	4	5	6
16. Taking care of family responsibilities?	1	2	3	4	5	6

17. Being useful to others?	1	2	3	4	5	6
18. Having no worries?	1	2	3	4	5	6
19. Your neighbourhood?	1	2	3	4	5	6
20. Your home, apartment, or place where you live?	1	2	3	4	5	6
21. Your job (if employed)?	1	2	3	4	5	6
22. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
23. Your education?	1	2	3	4	5	6
24. Being able to take care of your financial needs?	1	2	3	4	5	6
25. Doing things for fun?	1	2	3	4	5	6
26. Having a happy future?	1	2	3	4	5	6
27. Peace of mind?	1	2	3	4	5	6
28. Your faith in God?	1	2	3	4	5	6
29. Achieving your personal goals?	1	2	3	4	5	6
30. Your happiness in general?	1	2	3	4	5	6
31. Being satisfied with life?	1	2	3	4	5	6
32. Your personal appearance?	1	2	3	4	5	6
33. Are you to yourself?	1	2	3	4	5	6

Appendix O: Information sheet for second stage of the study

[INSERT SERVICE LOGO]

Psychological factors, pain and fatigue in cancer survivors

Participant Information Sheet

We would like to invite you to take part in a research study that is being conducted by Dawn Lindsay (Clinical Psychologist in Training, University of Bath). Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Why is this project being done?

Many cancer survivors experience physical symptoms, including pain and fatigue, once they have completed treatment. We know that feeling low about these symptoms, fearing that cancer may return in the future and worrying about health in general, are common and very normal for people who have finished treatment. However, sometimes people can experience anxiety, fears and a low mood at a level that becomes quite disruptive and intrusive to their everyday lives.

We would like to find out which psychological factors (e.g. feeling 'defeated' by physical symptoms or fearing that cancer may return in the future) have the biggest effect on mood, anxiety and quality of life. We would also like to explore whether what people think and feel is affected by the physical symptoms that they experience.
This should help us to design more effective psychological therapies to support people to manage their emotional wellbeing better.

Why have I been invited to take part?

We would like to invite people who are aged 18 years or above and:

- Have received a past diagnosis of cancer
- Have completed primary cancer treatment
- Do NOT have any existing co-morbid chronic physical health problems

What will I be asked to do if I take part?

You will be invited to complete a set of brief questionnaires that ask about different aspects of your wellbeing, including your physical and mental health. The questionnaires should take approximately 35 minutes to complete.

Once completed, please send the consent form and questionnaire pack back to the researcher in the pre-paid envelope.

What are the benefits?

Although there are no direct or immediate benefits to you completing this study, it is hoped and anticipated that the results of this study will help us to understand how the way in which people think and feel about their physical symptoms may lead to increased distress and reduced quality of life. This should help us to design and provide more effective and timely psychological help.

On return of your completed questionnaire pack you will receive a £5 gift voucher as a token of appreciation.

Will the information I give be kept confidential?

Yes. In accordance with the Data Protection Act of 1998, all of the information you provide will be handled in strict confidence and will be anonymised with your name and personal information removed. The data collected will be stored securely in locked cabinets and password protected computer files and only the research team will have access to this. Data will be kept for 5 years after the close of the study and destroyed after.

If the answers you provide in the questionnaires lead us to feel concerned about risk to your self or others, we may have to break confidentiality and discuss this with your Oncology team so that they can make contact with you and your GP to discuss your preferences and needs for additional support. We would discuss this with you first.

We will analyse the data collected and hope to report our findings within academic/health related journals and present them at conferences. The findings will also contribute to Dawn Lindsay's Doctorate in Clinical Psychology.

You will not be identified in any reports or publications arising from the study.

If you would like to receive a summary of the findings when the study is complete, then please indicate this at the end of the questionnaire pack.

What if I change my mind during the study?

If you decide to take part and then later change your mind at any point before the close of the project, you can withdraw without giving your reasons and if you wish, your data will be destroyed. Taking part, or otherwise, in the project will not affect any current or future treatment that you may receive.

Are there any risks?

We consider there to be minimal risk to participating. However, it may be possible that completing the questionnaires relating to your experiences raises some emotional or distressing feelings. You may complete the questionnaires on your own or with the support of family/friends. You may also contact Dawn Lindsay (primary researcher) if you would like support to complete the questionnaires, or if you have any queries.

If at any time you feel upset or distressed when completing the questionnaires, then please do not hesitate to contact one of the following sources of support:

- Dawn Lindsay (contact details below)
- Your Cancer Clinical Nurse Specialist or another member of your healthcare team

Any of the above people will be able to talk through your concerns with you and discuss options for further support, according to your wishes.

What if I have any further questions/concerns?

If you have any questions or concerns, please contact Dawn Lindsay in the first instance.

If you have any general questions about participating in a research study or if you require further advice or support, then you may contact your local Patient Advice and Liaison Service (PALS).

University Hospitals Bristol PALS

Telephone: 0117 342 1050

Email: psct@uhbristol.nhs.uk

Royal United Hospital, Bath PALS

Telephone: 01225 825656

Email: ruh-tr.PatientAdviceandLiaisonService@nhs.net

Gloucestershire Hospitals PALS

Telephone: 0800 019 3282

Text: 07827 281 266

Email: pals.gloucestershirehospitals@glos.nhs.uk

Salisbury NHS Foundation Trust PALS

Telephone: 0800 374 208

Email: customercare@salisbury.nhs.uk

Who has approved the study?

An independent ethics committee reviews all research in the NHS to ensure your safety, privacy, wellbeing and dignity. Approval for this study was given by the Department of Psychology's Ethics Committee at the University of Bath and the Black Country National Research Ethics Service (NRES) Committee.

What happens next?

Please take some time to decide if you would like to participate in the study. If you wish to participate then please sign the consent form and complete the questionnaires. Once complete, please return the questionnaire pack and signed consent form to the researcher in the pre-paid envelope. Alternatively, you may return the documents to your local oncology clinic and they will be collected by the researcher.

Contact details

Services

Please contact your named Cancer Clinical Nurse Specialist at your local clinic in the first instance, if you feel upset or distressed.

Local clinic details:

St Michael's Hospital, Bristol

Main reception: 0117 342 5325

Bristol Haematology and Oncology Centre

Main switchboard: 0117 923 0000

Royal United Hospital, Bath

Oncology outpatients: 01225 825097/825663

Gloucestershire Royal Hospital

Reception: 0300 422 2222

Cheltenham General Hospital

General Office Enquiries: 0300 422 4027

Salisbury District Hospital

01722 336262 extension. 4382

Research Team

Primary researcher

Dawn Lindsay

Clinical Psychologist in Training

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BA2 7AY

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Telephone: 01225 385506

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Research supervisor

Professor Paul Salkovskis

University of Bath

Email: p.m.salkovskis@bath.ac.uk

Additional support services:

Macmillan cancer support line

Telephone: **0808 808 00 00 (Mon-Fri 9am-8pm)**

Email: contactus@macmillan.org.uk

www.macmillan.org.uk

Tenovus, the cancer charity

Telephone: 0808 808 10 10 (365 days a year, 8am-8pm)

www.tenovus.org.uk

Penny Brohn UK

Telephone: 0303 3000 118 (Mon-Fri 9.30am-5pm)

Email: helpline@pennybrohn.org.uk

www.pennybrohn.org.uk

NHS 24

Telephone: 111 (24 hours a day)

Appendix P: Consent form for second part of study

UNIVERSITY OF BATH

Psychological factors, pain and fatigue in cancer survivors

Consent Form

1. I confirm that I have read the information sheet dated 20/11/2016 (Version 3) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that the information that I provide will be made anonymous and kept confidential, except in the circumstances where information is provided that may place myself or others at risk. ☐

4. I agree to take part in the above study. ☐

Name of participant (Print) _____ Signature of participant _____

Date _____

Please keep one signed copy of this consent form for your own records and return the other signed copy with your completed questionnaire pack in the envelope provided.